EXHIBIT D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)))	Master File No. 2:12-MD-02327 MDL 2327

THIS DOCUMENT RELATES TO ALL WAVE 4 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS:

Candy Breeden
Case No. 2:12cv04658

Stephanie Browley
Case No. 2:12cv04515

Wendy Happel
Case No. 2:12cv03889

Ella Howard
Case No. 2:12cv03976

Charlotte Humphreys
Case No. 2:12cv04810

Cathy Kimsey
Case No. 2:12cv04814

Melanie Turner
Case No. 2:12cv03847

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

DEPOSITION OF SAMANTHA JOY PULLIAM, M.D.

GENERAL TVT and TVT-O

Friday, March 31, 2017

Chapel Hill, North Carolina

10:40 a.m.

Reported by: Karen K. Kidwell, RMR, CRR, CLR

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DEPOSITION of SAMANTHA JOY PULLIAM, M.D., General TVT and TVT-O, a witness in the above-entitled action, taken on behalf of Plaintiffs, pursuant to the Federal Rules of Civil Procedures before KAREN K. KIDWELL, RMR, CRR, a Certified Shorthand Reporter, at Courtyard Chapel Hill, 100 Marriott Way, Chapel Hill, North Carolina, the 31st day of March, 2017, at 10:40 a.m.

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INSTRUCTIONS

FRIDAY, MARCH 31, 2017, CHAPEL HILL, NORTH CAROLINA

PROCEEDINGS

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SAMANTHA JOY PULLIAM, M.D.

being first duly sworn, testified as follows:

EXAMINATION

BY MS. WHITE:

Q. Dr. Pulliam, my name is Kimberly Wilson White, and I'm here to take your deposition in regards to you being designated as a general urogynecology expert in wave 4, right?

MR. RUMANEK: Correct.

BY MS. WHITE:

Q. Wave 4 litigation. So you know why you're here today?

A. I do.

Q. Okay. Very good. Have you ever given your deposition before?

A. I have not.

Q. Okay. Can you please state your name for the record?

A. Samantha Joy Pulliam.

Q. All right. Do you sometimes go by Mandy?

A. I do.

Q. What do your friends call you?

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A. My friends call me Mandy.
Q. Okay. And where do you live?
A. I current live in Chapel Hill.
Q. And how long have you lived in Chapel Hill?
A. Since January of 2016.
Q. Okay. And you've never been deposed before?
A. I have not.
Q. Okay. So do you understand that the court reporter just placed you under oath?
A. Yes.
Q. So your testimony here today is virtually -- is the same as giving testimony under oath in a court of law. You understand that?
A. I do.
Q. So since you have not been deposed before, I'm going to go through some deposition rules that your counsel might have already gone over with you. I'm going to be asking you questions today in regards to your opinions about TVT and TVT-O. Can we agree that when I ask you a question about TVT, we're referring to the Ethicon TVT retropubic device?
A. Yes.
Q. Okay. And then TVT-O is the TVT obturator

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device. Can we agree to that?
A. Yes.
Q. Okay. I'm going to be asking you questions. If you don't understand my question, ask me to rephrase it. I'll be glad to do that. If at any point during the deposition you need to take a break, I don't have a problem with that. The only thing I ask is that you answer the question that has been posed and you do not take breaks during my question.
A. Okay.
Q. Let's get through the question. You can take a break. So just to be clear, you have never given a deposition in a workers' compensation case?
A. No.
Q. Medical malpractice case?
A. No.
Q. And you've never been deposed in connection with a pelvic mesh case?
A. I have not.
Q. Okay. Have you ever testified in court?
A. I have not.
Q. You are probably the first doctor I've ever deposed in 22 years that has never been under oath before. Probably a good thing.

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Are you currently employed?
A. I am.
Q. How are you employed?
A. I work as a physician at the University of North Carolina at Chapel Hill.
Q. Okay. And you are soft-spoken. So I'm going to ask you to keep your voice up today, mainly for the court reporter. The court reporter here to my right is taking down everything that you say. This will be the official record of your testimony. So it's very important that she can hear your testimony.
A. Okay.
Q. So what -- what's your title with the university?
A. I'm the division director of urogynecology. There's a longer title that involves urogynecology and female pelvic reconstructive surgery. And that's within the Department of Obstetrics and Gynecology at the University of North Carolina.
Q. Okay. Did you just give me that longer title?
A. I did.
Q. And did you take over for Catherine

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Matthews?
A. Yes, I did.
Q. And did you know Dr. Matthews before she left?
A. I knew her, not well. I mean, I expect I've introduced -- been introduced to her at national meetings and maybe had a drink in a large group before.
Q. Okay. Did Catherine reach out to you about applying for this position at UNC?
A. No.
Q. Okay. Have you ever talked to Catherine about any testimony she's ever given under oath in regards to the mesh litigation?
A. Not that I recall.
Q. Okay. Are you aware that she, in fact, also serves as a general urogyn expert in the mesh litigation?
A. I was not aware of that.
Q. And did you receive and review any portion of her deposition testimony in regards to mesh litigation?
A. Not that I recall.
Q. So do you currently see patients?
A. Yes, I do.

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Q. Okay. Tell me a little bit about that. On what days do you see patients?
A. So I see patients a different day every week, probably on average three to four days a week.
Q. Okay. What do you do on the other days?
A. Well, sometimes I operate. I suppose that counts as seeing patients. And during the other days, I do work in terms of the administrative portion of my responsibility with regard to the division so making the schedule and working on the budget and things like that. I do teaching of residents and fellows within the university within the fellowship that's part of my division which is female pelvic medicine and reconstructive surgery so there's a fellowship there. We have three fellows and I teach them.
I do some work with the American Urogyn Society where I'm the quality chair which means I oversee the development of a registry and work that goes into designing quality measures to ensure that urogynecologic procedures and practices are performed to specific standards that are required by, for example, the Center for Medicare and Medicaid Services. I go to a lot of meetings.
Q. Okay. So let's break this down a little

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bit. You said that you see patients three to four days a week?
A. That's right.
Q. And then how many days a week do you teach?
A. Well, on some of those days that I'm doing -- working in the office or in the operating room, I'm also teaching. And then depending upon the week, there is a didactic conference on Wednesday mornings I'm responsible for running along with our fellowship director. And then, in addition to that, I do lectures and teaching of the residents on occasion.
Q. So do you teach in the classroom?
A. I give lectures sometimes or I'm usually more likely to do sort of an ad hoc teaching but not -- not a lot of classroom teaching, no.
Q. So when you say you're teaching, it's mainly with residents and fellows that are with you as you're diagnosing and seeing patients?
A. That's correct. Mainly.
Q. So how many days a week do you operate?
A. One to two.
Q. Do you currently surgically treat patients who have been diagnosed with stress urinary

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incontinence?
A. Yes, I do.
Q. So do you have your own set of patients that you see? For example, you'll see a patient who comes in, she is symptomatic for stress urinary incontinence. You would diagnose her and then perhaps do surgery on her?
A. Yes, I do. I have my own set of patients, and then I also oversee fellows who have their own sets of patients, and I ensure that they are learning and that they're taking good care of patients while they're seeing them.
Q. Okay. And then do you also treat patients who have been referred to you from other physicians?
A. I do, although I'm not sure I would differentiate between my own set of patients and patients who are referred to me by other physicians. That's really one in the same sort of idea.
I think there are a number of ways that a patient could come to me. They could be sent by another physician. They could find me themselves or they might be sent by the emergency room or some other referring source that's not specific to, you know, another private physician relationship.
Q. Okay. Do you do research?

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A. Yes, I think so. I mean, I think I'm not a basic science researcher typically, although I have been involved in basic science over the course of my career. That's not currently my effort. I do research in quality of care primarily at this point. But I'm also part of a larger group of urogynecologists, and we do clinical trials and some device trials as part of the larger group. So my name would be on protocols for pretty much the span of things.
Q. Okay. Tell me about this larger group of physicians.
MR. RUMANEK: Just -- just as another kind of deposition tip, since she's taking everything down, make sure she finishes her question all the way before you start answering. That's so that you're not talking over each other.
THE WITNESS: I understand.
BY MS. WHITE:
Q. And that wasn't a real good question. So what is this group of other physicians --
A. Right.
Q. -- that you've referred to that you all do clinical trials?
A. Right. So the division that I oversee is

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a division of urogynecology and female pelvic reconstructive surgery, and there are six physicians and a nurse practitioner in the division, and so we collaborate on research within that context. I think -- I'm new to this group, but literature review would show that most of the published papers from this group involve the work of multiple physicians in the group.

Q. Okay. Do you currently have clinical trials going on right now?

A. I -- we do currently have clinical trials going on right now, none that I personally am the lead physician or investigator on.

Q. Do any involve polypropylene transvaginal mesh products?

A. No, they do not. There is a research project that's involved Pelvetex, but we are the native tissue arm of that. So I guess in its extension, it's a multicentered trial. There may be other things besides native tissue that are used, but for our group, we have used -- we have not used -- we have only used the native tissue.

Q. Okay. So other than your position at UNC, your current position, do you receive income from any other source?

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A. Nothing comes to mind as a major source of income. I think I have received a little bit of income over the past probably seven years for some legal review that's never resulted either in deposition or sort of anything that's gone to court to the tune of maybe 3 or $4,000 over the course of the last ten years. But I don't remember much about it. I couldn't even tell you who -- who it was.

Q. Okay. Have you ever been -- so let's talk about that a little bit.

A. Okay.

Q. So you've been paid 3 to $4,000 to review a case. Would that be a medical malpractice case?

A. Yes, that's it.

Q. Okay. Have you currently been paid by J & J for any of your work involving this litigation, the mesh litigation, whether it's wave 1, 2, 3, or 4, have you been paid by J & J for being an expert in the mesh litigation?

A. No, I have not.

Q. Okay. Are you keeping track of your time?

A. I am.

Q. Okay. Why have you not submitted an invoice?

A. Well, my plan was to submit an invoice

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after this deposition, but it has -- it was rescheduled a couple of times, and so it's just been I was going to do it all together at the end of this sort of phase of this work. And this has stretched out so it just hasn't happened yet.

Q. Okay. I need to ask you some questions about the work that you've done since I don't have the invoices.

A. Okay.

Q. Okay. So to date, how much time have you spent working as a general urogyn expert for the mesh litigation?

MR. RUMANEK: Let me just make sure the question is clear. Are you talking about just her general, because she also worked on some case specific, and I just want to make sure you all are talking about the same.

BY MS. WHITE:

Q. Okay. Let's break that down. Okay?

A. Okay.

Q. Because we would have gone there anyways. So in terms of your general urogyn expert work, how many hours have you spent as of today's date excluding the 15 minutes we have been in the deposition?

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A. Okay. Well, I think to write the report that I submitted, probably -- I mean, I haven't totaled these, to be honest with you, but I think probably over 40 hours, maybe 43 hours or so on the generation of the report. And then probably over the last several weeks, I've spent maybe 10 hours or so reviewing the things that I wrote and working in preparation for this.

Q. What do you mean "for this"?

A. For this deposition.

Q. Okay. But prior to writing the report, did you do any research to get yourself in a position to write the report or does that 43 hours include all of that?

A. I would say that 43 hours includes all of that.

Q. Okay. So your testimony here today is that you've spent about 53 hours of time as a general urogyn expert for wave 4?

A. I think that's about how much time I've spent working on this case.

Q. But you have not submitted your invoice to J & J as of date because you're waiting until this deposition is over?

A. That's it.

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MR. RUMANEK: And I'll just note on the record that we can provide the invoice when we get it, and I think that will -- we can agree that will reflect the accurate time --

THE WITNESS: Absolutely.

MR. RUMANEK: -- to the best of her ability.

BY MS. WHITE:

Q. Okay. So now let's talk about case specific. In how many cases have you been designated a case specific urogyn expert for J & J?

A. So I'm not sure -- so designated and actually happened are probably two different kinds of questions. I -- I was given maybe three or four cases to review. And I reviewed a couple of those. But somewhere in the process of that, those were not things that went forward. So I -- I'm not sure designated meaning they were assigned to me. I'm sure that that's true. But I think in terms of actually going forward with being that expert, I haven't really spent a lot of time on that.

Q. Okay. I don't care whether or not the cases went forward.

A. Okay.

Q. I'm trying to ascertain how much time you

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have worked as an expert in which you're going to bill J & J.

A. I see. Probably about 15 hours, maybe a little bit less than that. I have spent less time -- actually, I mean, I've given -- written this down in my system, provided it for my secretary who keeps track of things, but I haven't looked at that because it was such an abrupt end to the process.

Q. Okay. So if I understand your testimony correctly, there is about 15 hours in case specific work that you've done that you have not billed J & J for yet?

A. That's right. And it's a very rough estimate.

Q. Okay. Well, do you think it could be less or more?

A. I don't know.

MR. RUMANEK: Object to the form.

BY MS. WHITE:

Q. And when do you plan to submit those invoices because those cases are over.

A. Right. So, they are. And I -- at least I assume so. I think my impression was that they were on hold. So I guess -- but I -- this had all transpired in a way that I seemed at this point,

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because this is the first time I've done this perhaps, to happen in a block. So my plan had been to submit the whole of it together at the end of these depositions which were initially planned to be closer together than now they apparently are.

Q. Did anyone tell you not to submit your invoices prior to this deposition?

MR. RUMANEK: Object to the form. I don't even -- that would necessarily involve I guess discussion with counsel. Don't tell her anything that you discussed with counsel to the extent that anybody else may have told you that.

THE WITNESS: I haven't discussed it with anyone else.

BY MS. WHITE:

Q. Okay. So, again, if I understand your testimony correctly, the work you've done on the case specific cases, which isn't connected to this depo today, you haven't invoiced J & J, but after this depo is over, you're going to invoice them for that work as well?

A. That's correct. I think, you know, some of this has to do with my new understanding of how this works. I know that at this point, now, there's sort of the general deposition, and then there are

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depositions regarding each individual patient. But I think when I went into this, that was a process that I was still learning about. So moving forward, I may do it differently. But that's what I've done this time.

Q. So are -- I want to get back to income from other sources.

A. Sure.

Q. Okay. I don't know if we covered that other than you're an expert for J & J, and you're going to get paid. You work for UNC?

A. That's correct.

Q. Do you receive income from any other service -- places?

A. You mean, am I employed? I have stocks and investments and all those sorts of things that are on my tax returns.

Q. No, no, income. Are you receiving income in any other capacity being on a board, serving as an expert for another pharmaceutical company? Are you receiving income?

A. I'm not on a board. I have not received income that I can recall from any other pharmaceutical company or any other entity.

Q. So your income -- income comes from UNC?

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A. Uh-huh.
Q. And then your time working as an expert for J & J?
A. That's right.
Q. Okay. Do you need to change that?
A. No. I don't need to change that except to say that the setup -- the arrangement for legal work with the University of North Carolina actually will pay the University of North Carolina for my services. In other words, the funds received don't come directly to me without going through them first.
And a large portion of the work that I do here will have monies that are intentionally directed towards resident education and other work within the university. So whenever I submit my bill, the income that is created from that is not going to come only to me. And it will be managed by university.
Q. Do you receive a portion of that income?
A. No.
Q. Okay. And I'm familiar -- I work with other experts at UNC. So I know what you're talking about. But -- but your department benefits from that income?
A. That's correct.
MR. RUMANEK: Object to the form.

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BY MS. WHITE:
Q. And, in fact, that money could be used for research that you personally wanted to do or clinical trials or -- I mean, you'll have -- that money will come to your division.
A. Right. Some of the funding will come to my division, and some to the greater department and the university. And there are, you know, specific things that I can do with it such as research and education. There are other things I cannot do with it.
Q. And who makes the decision for your department where that money goes?
A. The chair of the department.
Q. And who's your chair?
A. Daniel Clarke-Pearson. I must say I think he probably refines the decision. I suspect that it's a larger decision that is on the part of the medical school, but I'm not privy to those decisions.
Q. Okay. So I'm handing you what we have marked as Exhibit 1.
(Pulliam 1 was marked for identification.)
BY MS. WHITE:
Q. Okay. So I'm handing you what we have marked as Exhibit 1, which is the notice of your

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deposition. Then -- so, Dr. Pulliam, because I know you are new to this, I'm going to be handing to you exhibits that have exhibit stickers on them. At the end of the day, we have to all work together to make sure that those exhibits get back to the court reporter if it has a sticker on it.
MR. RUMANEK: So I'll just say to the best that you can, and we can all track them down again, if we need to. Once we're done with one, why don't we just try to create a stack in that corner of the table that is closer to the court reporter because there are other documents.
THE WITNESS: Okay, that's fine. I'll try to do that.
BY MS. WHITE:
Q. Have you seen Exhibit 1 prior to today?
A. Yes, I have.
Q. And what did you bring with you in response to your notice of deposition?
A. I think I brought here the things that you see before you. These are collection of the articles that I've used.
MR. RUMANEK: And I'll just note on the record, also, that we brought a copy of the report, a copy of her CV, and I've already given

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opposing counsel prior to the deposition so she could have a chance to look at it a thumb drive. We also have a reliance list which I think you already have as well.
MS. WHITE: Okay. And can we agree, Eric, that you will submit her invoices when you receive them?
MR. RUMANEK: Yes.
(Pulliam 2 was marked for identification.)
BY MS. WHITE:
Q. All right. And Exhibit 2 for the record is the thumb drive that you brought with you today?
A. Uh-huh.
Q. Okay? All right. How -- and you can put Exhibit 1 to the side.
MR. RUMANEK: Kim, let me just --
MS. WHITE: Yes, sir.
MR. RUMANEK: -- I just want to put it on the record because then tracking it down later may be difficult. There's a password protection on the thumb drive that is Pulliam -- PULLIAM2017.
MS. WHITE: I'm going to go ahead and write that for the court reporter. Pulliam2017?
MR. RUMANEK: There's no spaces.

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MS. WHITE: Okay. That's written at the bottom of the exhibit, Madame Court reporter. And, sadly, it's in the -- on the date line. All right. So you've got that then.
BY MS. WHITE:
Q. So what did you do to prepare for today's deposition?
MR. RUMANEK: And let me just -- I don't believe that she's asking you to discuss what you and I have discussed. I think she's asking more just general questions. Don't at any point during the deposition get into what you and I may have discussed.
BY MS. WHITE:
Q. So let's do it this way. Let's break it down. Did you meet with the lawyer sitting to your right in preparation for the deposition?
A. I did.
Q. Okay. And without discussing anything that you and he talked about during that meeting or meetings, tell me, first of all, how many times did you meet with him?
A. We met in -- at the University of North Carolina once a few weeks ago. I don't remember the date.

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Q. You don't remember the date?
A. And then this morning briefly -- I do not. And then this morning briefly. I think that's all of our face-to-face meetings.
Q. So you met here at UNC. How long did that meeting last?
A. Probably about two and a half or three hours. Maybe three and a half.
Q. So you think three and a half hours?
MR. RUMANEK: Object to the form.
THE WITNESS: Somewhere between two and a half and three and a half.
BY MS. WHITE:
Q. And there's something else that's going to happen today. He's going to object sometimes, hopefully not a lot. You need to answer the question unless he instructs you not to answer the question. But --
A. I understand.
Q. -- he'll be objecting for the record.
A. I understand.
Q. All right. So you met this morning. How long did you meet this morning?
A. Probably about an hour and 15 minutes.
Q. Okay. And then did you have any telephone

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conferences with either Eric or other lawyers or J & J representatives to get ready for today's deposition?
A. So there were no meetings with J & J representatives. And I have met with attorneys on the phone I want to say two or three times in the process of this, specifically within -- probably twice.
Q. Okay. So tell me, two or three times, let's take the first phone conference you had.
A. Okay.
Q. Do you remember when that occurred?
A. No.
Q. Okay. Was it -- was it within the last month?
A. Yes, it was within the last month.
Q. Was it during the month of March? Today is 31 so . . .
A. Most likely. I -- I am not very good with dates. And I was away on vacation last week so now I'm completely disrupted with regard to dates.
Q. All right. How long did that conversation last?
A. Probably about an hour and a half.
Q. Okay. So tell me about telephone

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conference number two. When did that happen?
A. Wednesday night.
Q. Okay.
A. Okay.
Q. And how long did that conversation last?
A. Again, about an hour and a half.
Q. Okay. Tell me about conversation number three. When did that occur?
A. So that was probably more remote and maybe was about 45 minutes.
Q. When did it occur?
A. I'm guessing in the end of February, but I couldn't be sure about the dates.
Q. Okay. But all this will be reflected on the invoices that you send to J & J?
A. Yes.
Q. Okay. All right. I want to talk to you a little bit about your background before we get into your report. Where did you go to high school?
A. I went to the Stony Brook School which is a small boarding school in Stony Brook, New York on Long Island.
Q. Where did you grow up?
A. Beckley, West Virginia.
Q. So did I.

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A. Did you really? No kidding.
Q. Yes, ma'am. Where did you go to high school? Oh, you said Stony Brook.
A. Did you go to Woodrow Wilson High School? I guess I'm not supposed to ask you questions.
Q. I went to --
MR. RUMANEK: She'll make an exception if you're talking about Beckley, West Virginia, I think.
MS. WHITE: I will. Also, the only doctor I've ever deposed from Beckley, West Virginia. No, I went to the country school. I went to Liberty. I could have went to Woodrow, but my parents would have had to have driven me to the bus stop.
THE WITNESS: I understand.
MS. WHITE: Hence I went to Liberty.
THE WITNESS: I understand.
BY MS. WHITE:
Q. Okay. So you went to Stony Brook. Okay. And after Stony Brook, you attended Duke?
A. I did.
(Pulliam 3 was marked for identification.)
BY MS. WHITE:
Q. Okay. I'm handing you what we have marked

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as Exhibit 3. It is the CV that made its way to me through your lawyer.
A. Okay. Thank you.
Q. You can take a look at that and why don't you tell me if that is the most up-to-date CV you have?
A. I believe so.
Q. Okay. All right. Let's talk about that. So after Duke, if I'm tracking it all correctly, you graduated in 1990?
A. That's right.
Q. Is that right?
A. Uh-huh.
Q. So what -- what did you do between 1990 and 1994 because it looks like to me there's a gap before you started med school.
A. There is, there is.
Q. So what was going on during those years?
A. So I did quite a few things during that time. I worked for a religious organization, Campus Crusade for Christ, and I worked counseling students at Syracuse University, and I worked --
Q. Excuse me. Where?
A. Counseling students at Syracuse University in New York. I worked in the summertime, for at

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least two summers, working in the inner city, soup kitchens and homeless shelters and so forth. Then I left Campus Crusade probably about a year and a half after I began that work and spent a brief time at Columbia University Teacher's College, thought I was going to pursue a degree in counseling psychology.
But during that time, I realized I really wanted to go to medical school. So I took a job then in an effort to become more involved in medicine at Sloan Kettering Cancer Center.
Q. Where?
A. Memorial Sloan Kettering Cancer Center in New York City, Manhattan, where I served as a research coordinator for clinical trials in the Department of Gastroenterology. And then I got into medical school and moved to Winston-Salem in the summer of 1994.
Q. Okay. Let me break some of that down. Okay, you -- after you graduated Duke, is the first thing you did was take a job for Campus Crusade for Christ?
A. That's correct.
Q. All right. So how long did you work for Campus Crusade for Christ?
A. I think about a year and a half.

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Q. Is it during that job where you were working in the inner city?
A. That's correct.
Q. Okay.
A. So that I worked with college students. So they were generally in college during the academic year, and then in the summertime, they weren't there and neither was I. So then I would work with those college students in a different setting which was in the inner city.
Q. Okay. So then I have it mid-1992, you left Campus Crusade for Christ?
A. I think that's the right year, yes.
Q. Okay. And then where did you go after that?
A. I moved to New York City.
Q. You moved to New York City. And what did you do in New York City?
A. I spent a semester in graduate school.
Q. All right. And that was at Columbia University Teacher's College?
A. That's correct.
Q. Okay. How long were you in grad school?
A. I was there for one semester.
Q. Okay. So why did you leave Columbia after

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one semester?
A. Well, I had intended a degree in counseling psychology. But the semester really made me realize that I needed a deeper understanding of medicine and biology and human biology. And so as a biology major at Duke, I had toyed with the idea of medical school, and I realized that that's what I needed to do. And so in order to move there, towards that goal as expeditiously as possible, I stopped the graduate program, worked in research, took the MCAT and pursued medical school.
Q. So prior to being enrolled at Columbia University, you had not taken the MCAT?
A. That's correct.
Q. Okay. So after Columbia University, after you left there, what did you do?
A. I worked at Sloan Kettering Cancer Center.
Q. Okay. All right. And how long were you there?
A. Probably about another year and a half.
Q. During this time, were you trying to get in med school?
A. So I was completing the application process to get into medical school. I took the MCAT, and once that was accomplished, I applied to medical

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school.
Q. Okay. Is Wake Forest the only med school you applied to?
A. No.
Q. Okay. Where else did you apply?
A. I applied to Columbia University and West Virginia University.
Q. And then Wake Forest University?
A. And Wake Forest University.
Q. Did you get in Columbia?
A. No, I did not.
Q. Did you get in WVU?
A. No, I did not.
Q. You got in Wake Forest?
A. I did.
Q. Well, my brother went to WVU about the same time you did so we got a lot of --
A. A lot of connections.
Q. A lot of connections. Okay. So then what year did you graduate medical school?
A. 1998.
Q. Okay. What kind of grades did you make in med school?
A. I believe I was in the upper third of my class. I participated in an alternative program. It

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was called the parallel curriculum. I don't think Wake Forest still has it, but it was a small group, didactic learning experience as opposed to a lecture hall which is a traditional medical school format, and so the class rank based on that was a little bit diluted and different because there weren't examinations and ranks so I don't know exactly where I was in the class rank.
Q. Okay. So after graduating medical school, did you enter into medical residency program?
A. I did.
Q. Okay. And that would be you were an intern in anatomic pathology at Mass General?
A. Correct.
Q. Was this the only residency program you tried to get into?
A. No, it wasn't.
Q. Okay. Tell me about the others you applied to.
A. I applied actually to pediatrics residency programs, and there's a long list, the names I don't recall. It's been a long time. I really wanted to be in Boston or in the Northeast. I think probably I would have been happy with New York or Washington, D.C. or Philadelphia so I concentrated my efforts

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there.
Q. So let me stop you there. Why did you really want to be in Boston?
A. Well, I had gone to high school on Long Island. I guess Boston's probably not right. I really wanted to be in New England or the Northeast. I went to high school on Long Island and I liked the New England area and Boston has a great reputation for training programs.
Q. Okay. So you tried to get into a peds residency program?
A. That's right.
Q. And was anatomic pathology your plan B?
A. It was.
Q. All right. So you go into the residency program. And help me here. When you say you're an intern, that was the first year of an official recognized residency program?
A. That's absolutely correct.
Q. Okay. All right. So it looks like to me you stayed there one year?
A. I did.
Q. Okay. Why did you leave that residency program?
A. Well, residency training is a very

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different experience than medical school. You focus in on, you know, one specific discipline. And pathology is sort of an interesting experience because you receive specimens to examine from many different disciplines and you're exposed to lots of things.

Massachusetts General Hospital where I did my pathology residency or internship had a vast surgical source for pathology specimens and a really excellent educational program and I was exposed to a lot of things there. I also learned what it was like to do pathology, and during the course of that year, I realized that I probably wasn't well cut out for pathology, and, in fact, I might prefer something that had a little more active role such as a surgical specialty and, also, that perhaps I talked too much to be a very good pathologist which is really a solitary experience.

So I -- I chose to pursue obstetrics and gynecology which was not pediatrics, but it was certainly part of my experience at Mass General to learn about OB/GYN, as part of my pathological -- pathological -- pathology exposure.

Q. All right. So during this anatomic pathology internship, did you apply to peds

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residency? Did you continue to try or is your testimony that you decided you wanted to go into OB/GYN, so hence you started down the OB/GYN road?

A. So I was conflicted. You know, I had gone down the pediatrics road in the past, and I think changing directions is always a challenge. And I -- I initially started in pediatrics, again, but realized at some point that OB/GYN would be a better option for me.

Q. So you did apply to peds?

A. That's correct.

Q. Okay. So then was OB/GYN kind of the plan B if you didn't get into the peds residency programs again?

A. You know, I suppose in hindsight, the answer to that is yes. But I think, also, you know, medicine is a process, and figuring out where you fit in medicine is sort of a process of self-discovery. And I think, you know, I would say that things evolve, you know. I mean, you realize where you belong over time. And certainly on this side of it, I would never turn back.

Q. Okay. Why don't you tell the jury what is anatomic pathology?

A. So patients go to surgery. And there

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is -- there are specimens that are taken. I mean, a prime example might be a cancer specimen that's removed and then determination about future treatment about the diagnosis is made based upon the microscopic examination of specimens. Also included in anatomic pathology are things like autopsy and understanding perhaps of what caused the death.

Q. How does -- how does anatomic pathology differ from clinical pathology?

A. Clinical pathology in general deals more with the laboratory and with, you know, blood samples and kind of liquids as opposed to solids I guess is a simple way to explain it.

Q. Okay. As you sit here today, you do not consider yourself a pathologist, correct?

MR. RUMANEK: Object to the form.

THE WITNESS: I've had pathology training and additional specific pathology training as it pertains to obstetrics and gynecology.

BY MS. WHITE:

Q. Okay. Simple question. Are you a pathologist?

A. I'm not a board-certified pathologist.

Q. Okay. And here at UNC, do you practice in the area of pathology?

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MR. RUMANEK: Object to the form.

THE WITNESS: I think that I interact with pathology almost every day, and certainly, I evaluate the pathology specimens of my patients when I perform hysterectomies, cystectomies, and other gynecologic procedures.

BY MS. WHITE:

Q. Okay. I just -- do you practice -- are you a practicing pathologist?

A. Is my -- no, I'm employed through the OB/GYN department at the University of North Carolina.

Q. Have you ever held yourself out as a pathologist at any institution where you've worked?

MR. RUMANEK: Object to form.

THE WITNESS: I have not held myself out as a pathologist at any institution where I've worked since I was a fellow in pathology.

BY MS. WHITE:

Q. Okay. And then you talked about other training you've had in pathology after the one year in anatomic pathology at Mass General. Please tell the jury about that.

A. So training in pathology, the assessment and understanding of pathologic specimens in

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obstetrics and gynecology is part of the training program there, part of the residency training.
Q. Have you ever written and published in a peer-reviewed journal anything pertaining to -- to pathology or pathology research that you've done?
A. No, I don't believe I have.
Q. All right. So did you apply to Mass General's OB/GYN residency program?
A. No, I did not. Not as an initial application.
Q. Okay. So where all did you apply because you -- basically, you're leaving what would have been a three-year residency program in pathology?
A. That's right.
Q. Okay. And you did complete the one year?
A. That's right.
Q. Okay. What were your grades like?
A. There are no grades in a residency program. I was urged to stay, so it's not -- you know -- I did well in the program. My evaluations were good.
Q. Okay. Where all did you apply to OB/GYN residency?
A. So I didn't apply to OB/GYN residency programs. I took an available position at what's now

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the university -- I think the University of Toledo Medical College of Ohio. And I moved there to spend my first year as an intern in obstetrics and gynecology there.
Q. Why did you choose Medical College of Ohio?
A. Among the available programs, it was the best program that I could be in. Lou Weinstein, who is chair of the department there, is known as a former chair I think of the American College of Obstetrics and Gynecology and a prominent person in OB/GYN. And so I thought it would be a good training program.
Q. Do you consider it a leading academic medical institution?
MR. RUMANEK: Object to form.
THE WITNESS: I would say that it is a leading academic medical institution. It's not Harvard University, but it's -- it provides a ACGME accredited obstetrics and gynecology training.
BY MS. WHITE:
Q. Okay. So why did you leave there after one year?
A. So as I mentioned, that was an available

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training program. And sometimes in medical training, you go where you must. And when an opportunity arose to be back in a place that I wanted to be, I for personal reasons chose to pursue work at Boston Medical Center where there was an available spot for a person in second year of residency.
Q. Okay. So what do you mean by "for personal reasons"?
A. Well, there's certainly more to life than work. There are relationships and other aspects of life that are compelling to almost everyone, and that was true for me.
Q. Okay. So did you -- did you have a significant other or family in Boston?
A. I had significant attachments in Boston.
Q. Okay. So you leave Medical College of Ohio, it's your testimony, because you had personal relationships in Boston, and you wanted to get to Boston?
A. That's right.
Q. Okay. All right. So you were at Boston Medical Center from July 2000 to June of 2001. And then it looks like to me there's a break.
A. There was no break.
Q. Okay. Then your CV is incorrect.

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A. That's possibly true.
Q. Okay.
A. That's possibly true. What I did there was I completed a year of residency at Boston Medical Center.
Q. Okay.
A. Part of that year involved three months spent at Massachusetts General Hospital delivering babies.
Q. Okay.
A. And during that time, I was recruited to be part of the third year OB/GYN class at Massachusetts General Hospital, Brigham and Women's Hospital. They had a vacancy, and I applied and was accepted to be part of that program.
Q. Okay. So what I want you to do, Doctor, is take a look at your CV.
A. Yes.
Q. And correct the mistake. Because it says here June 2000 through June 2001, you were a resident OB/GYN Boston Medical Center.
A. Yes.
Q. And then we jump to July of 2002 --
A. You're correct. That 2 should be a 1.
Q. Okay.

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A. I was there for two years.
Q. All right. Makes sense. So let's back up for a second.
A. Okay.
Q. From -- in -- during your time at Medical College of Ohio, did you surgically treat stress urinary incontinence?
A. I would say as an intern, it's possible that I participated in cases that included stress urinary incontinence, but that's not the major role of an intern in any training program.
Q. Okay. Did you implant polypropylene mesh devices during that time?
A. I don't -- I don't recall.
MR. RUMANEK: Wait, wait. Make sure she finishes her question.
THE WITNESS: I'm sorry.
BY MS. WHITE:
Q. Did you implant -- did you surgically implant polypropylene mesh devices for the treatment of stress urinary incontinence while you were at Medical College of Ohio?
A. I don't recall. I'm considering my time spent with the urogynecologist there, and I know I did spend time with him, but I don't recall if he was

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performing those procedures at the time and that his choice to perform them would be the only reason I would have participated in a surgery.
Q. Okay. So you don't recall any experience or exposure to polypropylene mesh devices during that time at Medical College of Ohio?
MR. RUMANEK: Object to form.
BY MS. WHITE:
Q. You can answer.
A. I don't recall.
Q. Okay. So then your opinions in this case would not be based upon experience with polypropylene mesh going back to 1999?
MR. RUMANEK: Object to the form.
THE WITNESS: I think that my experience with polypropylene mesh may be not only based on surgical experience. Certainly, there is literature that we have access to at that point, in addition to teaching in didactics that I would be exposed to in a residency program.
BY MS. WHITE:
Q. Okay. I don't understand your answer.
A. So in a training program, there is exposure on a number of levels. There are senior residents who perform with supervision procedures,

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and there are very junior residents who may observe or interact with attending physicians about a number of different things. But they're rarely performing things independently or actually doing almost anything except perhaps a cesarean section which is a different kind of focus for the intern.
So I don't necessarily recall actually placing mesh myself, but I'm not sure that I would do anything myself as an intern. I know that that's not the case.
Q. All right. So during your one year at Boston Medical Center, did you become familiar with or implant polypropylene mesh devices in women for the treatment of stress urinary incontinence?
A. So at Boston Medical Center, I know that we were -- we meaning the larger Department of Obstetrics and Gynecology -- using mesh implants. I participated in surgeries that were -- along with urogynecologists there. Whether I specifically placed the mesh implants or assisted or were part of that experience, yeah, I think so.
Q. Okay. Well, your expert report --
A. Right.
Q. -- which you submitted to the court in this case --

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A. Right.
Q. -- says that you began placing mesh ten years ago.
A. That's right.
Q. Okay. So can I rely upon what you put in your report or are you changing your testimony?
MR. RUMANEK: Object to the form.
THE WITNESS: So I think that ten years ago was 2006, 2007. And there are different levels of placing mesh. I would say that most of the things that I did as a resident in training were part of a learning process. Sure, I was involved, but I can't say that I would be the primary person responsible for placing mesh.
BY MS. WHITE:
Q. Okay. So you're changing your testimony?
MR. RUMANEK: No, she's not changing it. Hold on just a sec. She's not changing her testimony.
MS. WHITE: Okay. I'm going to ask her questions and give her plenty of opportunity to explain.
MR. RUMANEK: And that was commentary. That wasn't a question.

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BY MS. WHITE:
Q. So to be clear, did you -- did you place polypropylene mesh -- surgically place polypropylene mesh for the treatment of stress urinary incontinence between June -- July 2000 and June 2001?
A. I participated in surgeries where polypropylene mesh was placed.
Q. Okay. And what types of surgeries did you participate in where polypropylene mesh was implanted? And, again, we're talking July 2000 through June of 2001.
A. So I would need to look at a case list from that point in time to tell you specific types of procedures that I participated in. Typical procedures that probably I participated in as a resident at that time would include suburethral slings and sacrocolpopexies.
Q. Do you remember what manufacturers' products you were using July 2000, June 2001 for these surgeries?
A. I couldn't be sure.
Q. And you say you would need a case list to know for sure. What do you mean by that?
A. So a case list would be a record of the patients that were involved in the care that I

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provided at the time.
Q. All right. So let's do it this way. How many surgeries were you involved in where mesh was implanted for the treatment of stress urinary incontinence from July of 2000 through June of 2001?
A. Anything that I would say would be a guess.
Q. Okay. Well, you're the expert. And you've just testified that you were involved in these surgeries --
A. Right.
Q. -- and all of this is a basis for your opinion.
A. Right.
Q. So I'm asking you how many were you involved in from July of 2000 through June of 2001?
MR. RUMANEK: To the best -- to best of your knowledge.
THE WITNESS: Right. So what you're asking me is to tell you when I was a second year resident in training how many procedures that I did involved mesh. Is that right?
BY MS. WHITE:
Q. Yes, ma'am.
A. Okay. I'm going to guess more than 20 and

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less than 40.
Q. Okay. And were you the lead surgeon implanting the suburethral slings?
A. As a second year resident in training, no, I was not.
Q. How much are you being paid for serving as an expert for J & J?
A. So the fees that I'm paid are determined by the University of North Carolina. And I believe they're about $600 an hour.
Q. Okay. So other than the suburethral slings, what was the other procedure that involved mesh?
A. Sacrocolpopexy.
Q. Okay. And what type of mesh product was used for that procedure?
A. Likely at that point, a polypropylene mesh or a Mersilene mesh, which is polyester.
Q. And how many of those procedures did you participate in from July of 2000 through June of 2001?
A. Probably -- probably five or less.
Q. Who was the head of that residency program?
A. The residency director was Callie

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Varaklis.
Q. Can you spell that last name?
A. I believe so. V-a-r-a-k-l-i-s.
Q. Okay. So now let's go to Massachusetts General Hospital. Oh, wait, first. Let me talk to you a little bit about your experience with the polypropylene sling procedures. How many complications were involved in the more than 20 less than 40 surgeries you were involved in?
MR. RUMANEK: Object to the form.
THE WITNESS: So how many complications were involved within that year?
BY MS. WHITE:
Q. Yes, ma'am.
A. I'll tell you a couple of things. One is that that one year in isolation was quite a long time ago so I'm not sure I could say reliably how many individual complications there were between 2000 and 2001.
Q. Yes, ma'am.
A. Yeah, I'm not sure I could say. I -- it would be very unreliable for me to do that, and I probably need to go back and look through the medical records of that list of cases to understand what the complication number was.

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Q. But you're not going to be able to have access to that case list.
A. That's right.
Q. Right? You're not going to be able to access the case list to know if you did more than 20 or less than 40, right?
A. That's correct.
Q. Okay. So let's go to July of 2001, June of 2003. While I guess this would have been your second year of a residency in OB/GYN?
A. So there would be an intern year and then the year at Boston Medical Center, which would be the second year. So this would be the third year of my OB/GYN training. And, yeah, I guess the second year of residency.
Q. So were you involved in the surgical placement of polypropylene meshes for the treatment of stress urinary incontinence during this time so --
A. Yes.
Q. -- July of 2001 -- June of 2003?
A. Yes.
Q. And did you perform those surgeries on your own?
A. No.
Q. Okay. And who was your residency director

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at Mass General?
A. There were two different residency directors at Mass General. And I'm not going to be able to pull either name. It will come to me during the course of this time.
Q. You say it will come to you?
A. I'm sure it will, but it's not on the tip of my tongue right now.
MR. RUMANEK: Whenever it pops into your head, it will be in the middle of an answer of some other question, I'm sure.
THE WITNESS: It may be in the middle of an answer to some --
MR. RUMANEK: You can say -- you can answer it.
BY MS. WHITE:
Q. That will be fine. How many surgeries were you involved in during this two-year period involving mesh if you know?
A. I don't know exactly. What I can tell you is that the American College of Graduate Medical Education carries a minimum number of surgeries that you're required to participate in to complete a residency, and those are published every year.
And I graduated from residency program.

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And so I know that with confidence I met those numbers. I don't know what those specific numbers were then and I don't know what they are now. So I -- was it more than 20 and less than 40? Possibly.
Q. But it didn't require you to use mesh in the surgical procedures?
A. No, it did not. It did not. But I did participate in surgeries that used mesh. I don't -- I can't, again, give you a number.
Q. Okay. Have you -- going back to your pathology, have you ever worked as a pathologist at any medical facility other than the one year that you did your internship at Mass General?
MR. RUMANEK: Object to form.
THE WITNESS: So I believe you asked me previously, and I've not been employed since I was an instructor -- not an instructor -- what is it, clinical something in pathology at Massachusetts General Hospital.
BY MS. WHITE:
Q. Okay. And during your anatomic pathology internship year, did you gain any sort of knowledge or study polypropylene mesh explanted from a woman who had been surgically implanted with that material?
A. Not to my recollection, no.

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Q. Okay. So you complete the OB/GYN residency program at Mass General?
A. That's right.
Q. Now, could you have sat for board certification after you completed your residency program?
A. Board certification in?
Q. In OB/GYN?
A. So board certification for OB/GYN comes in two steps. There's a written examination that you are permitted to sit for at the conclusion of the residency program. And I did sit for that within a couple of weeks of the completion of the residency program and passed that exam.
And then following that, there is the requirement of the collection of what's called a case list which basically is a record of your own experience within certain categories to sort of establish examples of your own practice. And then there's an oral board examination that occurs generally some years later after the completion of the residency program.
So that's how I did it. I sat for the available part of the written examination, and then I took an oral examination some years later.

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Q. Okay. I think I understand that. But you could have taken the oral exam years earlier, right, than what you did?
A. So -- let me just look at what year I took that. There's a -- and it changes all the time how -- what the length of time is between the time you complete and the time you are allowed to complete your case list, the time you take the written examination and the time you're allowed to submit your case list.
And it may have been -- and then also the American College of Obstetrics and Gynecology for a while did not allow individuals who participated in fellowships to take the board examination while they were in a fellowship. And then there are individual fellowships that won't allow you to take the board examination. So I would say that I took the board examination as soon as I was able to do so.
Q. Okay. And are you board-certified in -- a board-certified OB/GYN?
A. I am.
Q. Okay. All right. So after Mass General, then you I guess applied for or compete for a fellowship in female pelvic medicine and reconstructive surgery at Mount Auburn?

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A. That's correct.
Q. And am I correct that that was something you had to compete for?
A. Right. So there -- compete is a -- I guess it's competition. I mean, the Mount Auburn Hospital actually was not sure if they were going to offer a fellowship at the time. And so once they determined I think they were going to do that, I did interview there, and they invited me to be there.
So I guess in a way that you would compete for another job there's competition there. I don't know who my competition was.
Q. Okay. Did you apply for other fellowships in addition to the one at Mount Auburn?
A. I did, I did.
Q. And did you get into other fellowships?
MR. RUMANEK: Object to form.
THE WITNESS: So --
BY MS. WHITE:
Q. Fellowship programs?
A. Right. So the match system isn't such that you get into -- it's not where you get -- you don't get multiple job offers necessarily.
Q. Okay. So I guess what I'm asking you was Mount Auburn Hospital, this fellowship program in

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female pelvic medicine and reconstructive surgery, was this your first choice?
A. No, it wasn't my first choice.
Q. Okay. What was your first choice?
A. I think I wanted to go to Oregon.
Q. Okay. And why did you go want to go to Oregon?
A. Adventure.
Q. Okay. So what stopped you from going to Oregon?
A. I wasn't offered the position.
Q. Okay. And what position would that have been?
A. It would have been a similar fellowship at Oregon Health Sciences University.
Q. Okay. Do you remember any of the manufacturers of the polypropylene mesh devices that you surgically implanted to women during your time at Mass General? I understand you weren't the lead surgeon, but the cases you were involved in?
A. Not off the top of my head, no. I think -- no, not off the top of my head.
Q. Okay. Do you mean that it might come to you or --
A. No.

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Q. Or you just don't know?
A. I don't mean that it might come to me. I think more I mean that I wasn't necessarily familiar with the brands of anything at that point. I mean, in a residency program, you know, those are things that are brought to you, not that you select. And their selection process is really dependent upon the attending physician who does that selection.
Q. Okay. So during your residency program at Mass General, July 2001 through June of 2003, what were the surgical options for stress urinary incontinence, back 2001-2003.
A. So do you mean the ones that were to my knowledge available at Massachusetts General Hospital?
Q. Yes, ma'am.
A. Okay. So I would say that the ones I participated in were suburethral slings and urethropexies, Burch urethropexy. Were you only -- I'm sorry -- specifically asking about urinary incontinence or --
Q. Yes.
A. Yeah, I think -- and possibly a collagen injection into the urethra. There may have been other options that I wasn't exposed to that are

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available. It's hard for me to comment on the expertise of physicians practicing there over and above the things that I participated in, but that doesn't mean they weren't there.

Q. Just so the record's clear, though, during your time at Mass General, is that where you first received training in the diagnosis and treatment of stress urinary incontinence or did that start back at the Medical College of Ohio?

A. Right. I think that probably started back at the Medical College of Ohio. Every year of residency has sort of a different focus. Doesn't mean that you're not exposed to the other things, but the first year of residency, you might pick up some things about urinary incontinence, but it might more uniquely pertain to patients who are pregnant.

Q. Okay. All right. So you're first introduced to diagnosis and treatment of stress urinary incontinence during your -- at Medical College of Ohio?

A. And actually, I mean, the truth is that within the context of my residency training, that would be my first exposure. But I think, you know, medical school certainly provides exposure to that as well.

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Q. Okay. All right. But during that first year of the internship, that first year at Medical College of Ohio, is that -- was that the first time that you -- you were active in the diagnosis and treatment of a patient who had stress urinary incontinence?

A. I -- possibly. I mean, I think as a medical student, I participated in both urology and OB/GYN courses. So as a medical student, to the extent that medical students are, I would have been involved in the exposure to evaluation and treatment of those patients.

Q. All right. Your fellowship began in July of 2003. Who -- who was the director of this fellowship program?

A. Peter Rosenblatt.

MR. RUMANEK: Kim, we have been going about an hour. Whenever it's a good time for a break.

MS. WHITE: We can take a break now.

(A recess transpired from 11:48 a.m. until 11:55 a.m.)

BY MS. WHITE:

Q. All right. So let's talk about your fellowship. I think you just testified that it's

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Peter Rosenblatt who was the fellowship director?

A. That's correct.

Q. Okay. And tell me a little bit about the difference between a fellowship and a residency program.

A. So I think the difference between the programs really has to do with what the focus is. Obstetrics and gynecology is a discipline, and there is a certain sort of criteria for training that is determined by the American College of Graduate Medical Education and also by the American Board of Obstetrics and Gynecology. And so training programs are designed to fulfill those requirements with regard to the topics included in obstetrics and gynecology. Female pelvic medicine and reconstructive surgery is a smaller area within the field of obstetrics and gynecology.

And so fellowship training there is designed to meet those standards or specific educational objectives and to allow someone to fulfill all the requirements for board certification for those things. The focus is narrower generally in a fellowship and there's some effort to do a little bit of a deeper dive into some, in this case, specific surgical techniques and maybe some more --

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more specific and definitive knowledge on specific areas.

A general obstetric -- obstetrician/gynecologist might know some things about urinary incontinence, for example. A female pelvic medicine and reconstructive surgeon would be expected to know more, again have more experience in surgery based on their fellowship training.

Q. Okay. During your fellowship at Mount Auburn with Dr. Rosenblatt, I guess he was your boss, right?

A. He was a fellowship director, correct.

Q. Yeah. Did you diagnose and treat stress urinary incontinence?

A. With his oversight, yes.

Q. Okay. Yeah. So let's talk about that. Did you have your own patients during this fellowship program?

A. So not at the beginning, but as things developed, yes. There are different criteria for oversight that are part of a training program.

For example, for someone who has limited experience there might be direct oversight. The patient that I see I see, and the attending physician is there watching every word I say, correcting every

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word I say, so forth. As you grow in your experience, that responsibility changes from being, you know, direct oversight to indirect oversight and then to consultation as you sort of mature through the training process.

Q. Okay. Well, let's break it down by year. Year July 2003 to July 2004, did you see -- did you have your own patients that you diagnosed and treated for stress urinary incontinence?

A. I don't believe I did.

Q. Okay. So July 2004 to July 2005, did you have your own patients that you diagnosed and treated for stress urinary incontinence?

A. So I think the answer there is possibly, but let me just offer a caveat here that when you say "my own," I think there are sort of degrees of that. One would be in a sense of billing, right, did I sign the billing form so that I personally was sort of reimbursed and held accountable for that or did Peter Rosenblatt or one of the other doctors there do that. And those specific things, which would be one of the criteria in training that I would think of as my own, those things are evolving as well.

For example, now, in a fellowship training program, at no time during the three years of

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fellowship is a fellow ever independently billing. At the time that I was a fellow then, the rules were a little bit different. But the oversight was not dependent upon those billing rules.

So, you know, as I made my way through my second year, I think there were more situations in which I behaved not with direct oversight but with indirect oversight. And a fellowship is really defined by the oversight. So the second year has less oversight than the first year.

Q. Okay. That makes sense. And then the third year and what I'm really talking about is where you are the physician that's along with the patient making the decisions and directing the care. Okay?

So by year three, did you have your own patients where you're directing the care?

A. So I saw patients separate from Peter Rosenblatt. But I never operated independently to my recollection on patients who had urinary incontinence or pelvic organ prolapse. And so all of the patients would still cycle through the oversight of Peter Rosenblatt or one of the other urogynecologists there.

Q. Did you have a good relationship with Dr. Rosenblatt?

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A. I would say yes.

Q. Okay. And are you still in touch with him today?

A. Sure.

Q. Okay. Are you all friends?

A. We're colleagues. I mean, yes, I think we're friends.

Q. Okay. And I think you talk in your report, he's -- he's someone that you -- is it fair to say he's someone you look up to?

A. I regard him highly, yes.

Q. Okay. And has he been a mentor of yours in the area of female reconstructive surgery?

A. Absolutely. I mean, I think that's what it means to have a relationship as a trainer and a trainee. It certainly is true that the longer you go after you've been away from your training, the more you develop your own independent style. But there are probably still things I would talk with him about if they came up.

Q. And, well, do you view him as someone who has certainly helped you -- helped you advance your career?

MR. RUMANEK: Object to the form.

THE WITNESS: So yes and no. I mean, I

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think he has certainly supported me and, when called upon, given me advice and opportunity. On the other hand, I mean, quite frankly, I've worked hard to advance my own career. And -- you know, I think that's -- that's the way -- the way it works.

BY MS. WHITE:

Q. Well, has he ever served as like a reference for you in a professional capacity?

A. I think actually as part of the fellowship director, he has to.

Q. Is that a yes?

A. Yes. That's a yes.

Q. And during this fellowship, and correct me if I'm wrong, is -- is this the first time that you utilized the Ethicon TVT product? And we agreed that TVT means TVT Retropubic.

A. To be honest, as we said before, I wasn't 100 percent aware of the brands of the products that were used at Massachusetts General Hospital or at Brigham and Women's Hospital where I also operated, and so I couldn't say absolutely. I know that we did use Ethicon products then. But I don't -- I can't say for sure that I didn't use them previously.

Q. Well, did you have contact or

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communications with Ethicon sales reps during your fellowship program?
A. So within the context of my fellowship program, there was certainly contact on the part of the practice. Peter Rosenblatt, other physicians, attendings in the practice with Ethicon. And I was associated with them, whether I was assisting in surgery, conversing with the reps in those contexts, possibly I did.
Q. Let's do it this way.
A. Okay.
Q. Because you're serving as an expert --
A. Right.
Q. -- testifying about the safety and efficacy of TVT and TVT-O on behalf of Ethicon; is that right?
A. That's correct.
Q. Okay. So when is the first time that you recall using -- knowing that you were using a TVT-O product for the surgical treatment of stress urinary incontinence?
A. So I'm not sure I could put an actual date on it, but that was definitely within my fellowship. In other words, I couldn't say it was this date at this time. I -- there's just no way I can do that.

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It's been too long and it's not something that I would keep track of in my head.
Q. So you're testifying that you don't know when you first used the TVT product?
MR. RUMANEK: Object to the form. Mischaracterizes her testimony.
BY MS. WHITE:
Q. Please clear it up for me.
A. I am testifying that during the course of my fellowship, I did use Ethicon products. I am not sure that I can give you a specific date.
Q. I'm not asking for a specific date.
MR. RUMANEK: But she's answered generally.
BY MS. WHITE:
Q. Okay. Did you use the TVT product for the surgical treatment of stress urinary incontinence during your fellowship program?
A. Yes.
Q. Did you use the TVT-O product during your fellowship?
A. Yes.
Q. Okay. And how did you become familiar or introduced to the TVT medical device?
A. Familiar in the sense of what?

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Q. Well, how did you learn about it? Like was it something that Mount Auburn stocked and you were forced to use it? How do you recall becoming familiar with the product for the first time?
A. So there are probably a number of ways that I became familiar with the product. One would be that at the time, this is when slings, Ethicon and others, were becoming more commonly used. And so there was a buzz, right? Whether that's with my fellow trainees or with attendings, both within my fellowship or outside, would talk about them. They were -- there was information present in didactic sessions.
We did use the products and we had representatives provide teaching and those sorts of educational opportunities during that time. There were presentations at national conferences and probably advertising booths at national conferences, although I don't recall any of those specifically. I don't generally spend a lot of time in those places. But those are all opportunities for me to become aware of Ethicon and Ethicon products.
I think Ethicon is a leader in these types of products. So certainly they were one of the most common that we were exposed to during that time --

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that I was exposed to during that time.
Q. Do you know whether or not Dr. Rosenblatt was a paid consultant for Ethicon during the years you were in the fellowship program, July 2003 to June of 2006?
A. I've never been privy to Dr. Rosenblatt's financial arrangements.
Q. Is that a yes or a no?
A. No, I don't know. I don't know.
Q. Would -- is that something you would have wanted to known back July 2003-2006 whether or not your fellowship director had a business relationship with Ethicon?
MR. RUMANEK: Object to form.
THE WITNESS: What I would say that I did know about Peter Rosenblatt was that he is a businessman in addition to an excellent physician and an excellent teacher, and I knew that he had financial arrangements, as I assume that most people who did teaching for companies that did these mesh products have financial arrangements.
I couldn't tell you the nature of the financial arrangement, with whom he had them or how much money he made. But I assumed that there were

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some of those there, but that's an assumption on my part, not based on any specific information that Dr. Rosenblatt gave me. And so would it have made a difference that he had a specific arrangement with Ethicon? No.

Q. Do you think having a paid relationship with a pharmaceutical company or a medical device company makes a physician biased for or against a product?

MR. RUMANEK: Object to the form.

THE WITNESS: So I think to a great degree, it's important for physicians to interact with pharmaceutical companies and that that doesn't necessarily make someone a biased person. I think that the question of bias is really a hard one to figure out specifically and there are many different things that go into it. Bias may be present because someone really thinks a good -- a procedure is good.

And then there's bias -- you know, whether that's because there's been financial incentive, that's another question. That's certainly another kind of bias, but there are many kinds of bias.

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BY MS. WHITE:

Q. Do you think that -- or let me ask you this: Did Dr. Rosenblatt's endorsement of TVT and TVT-O during your fellowship impact your decision to utilize TVT and/or TVT-O as a form of treatment for stress urinary incontinence?

MR. RUMANEK: Object to form.

THE WITNESS: So within the context of my fellowship, Ethicon was certainly not the only set of products that I was exposed to. In fact, I probably couldn't name all of the types of products that I was exposed to during my fellowship even with regard to retropubic slings. So I would have to say no, that's not probably where or why I decided to use Ethicon products.

BY MS. WHITE:

Q. Okay. So your testimony is that Dr. Rosenblatt had nothing to do with your decision to utilize TVT or TVT-O?

A. That was not my testimony.

MR. RUMANEK: Hold on. Just let me object to the form. Mischaracterizes her testimony.

BY MS. WHITE:

Q. So your testimony is that Dr. Rosenblatt

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had nothing to do with your decision to use TVT or TVT-O during July of 2003 through June of 2006 for the treatment of stress urinary incontinence?

MR. RUMANEK: Object to the form. She's -- her testimony is what her testimony is. If you want to ask her a question. Her testimony speaks for itself.

BY MS. WHITE:

Q. So let me ask you that again because I'm not sure I got your answer. I'm really not, Doctor. And I apologize.

Did Dr. Rosenblatt --

MR. RUMANEK: Hold on. Why don't you -- the question -- reread the answer.

MS. WHITE: I'm going to ask a new question.

MR. RUMANEK: Okay.

MS. WHITE: This is my deposition. I'm certainly allowed to do that.

BY MS. WHITE:

Q. So did Dr. Rosenblatt have anything to do with your decision to utilize TVT or TVT-O for the surgical treatment of stress urinary incontinence between July of 2003 and June of 2006?

MR. RUMANEK: Object to the form.

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THE WITNESS: Dr. Rosenblatt exposed me to a broad variety of brands and options for the treatment of stress urinary incontinence. And as my teacher, certainly influenced both my expertise and my selection of products in that way.

BY MS. WHITE:

Q. Do you know whether or not Dr. Rosenblatt has ever received education grants from Ethicon?

A. I don't know.

Q. Do you know whether or not Dr. Rosenblatt has ever received research funding from Ethicon?

A. I don't know.

Q. If you were aware that during your years that you were in the fellowship program that he was receiving hundreds of thousands of dollars from Ethicon, would that have influenced your perspective of TVT, TVT-O or other Ethicon products for the use of stress urinary incontinence?

MR. RUMANEK: Object to the form.

THE WITNESS: My opinion of Dr. Rosenblatt is a broad-based opinion based on my interpersonal relationship with him. So no, I don't -- I don't think that information would have added or detracted anything from what I

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already know of Dr. Rosenblatt.
BY MS. WHITE:
Q. I didn't ask you about Dr. Rosenblatt. I said, if you would have been aware during your fellowship years that he was receiving hundreds of thousands of dollars as a paid consultant for Ethicon, would that have influenced whether or not you used TVT and TVT-O for the treatment of stress urinary incontinence in your patients?
MR. RUMANEK: Object to the form. Asked and answered.
THE WITNESS: My decision to use TVT and TVT-O in my patients was based on my understanding of the literature and my experience with the product as I had in residency, so, no, it wouldn't have.
BY MS. WHITE:
Q. So according to your expert report, during your fellowship, you yourself attended training that was put on by GyneCare and Ethicon?
A. Yes.
Q. So that's correct, you -- while you were a fellow, you attended GyneCare Ethicon training?
A. That's correct.
Q. Okay. And did you attend that training to

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learn how to surgically implant TVT?
A. No, I didn't.
Q. Okay. So during your fellowship years, when you attended these GyneCare Ethicon professional education activities, what were you learning how to do? What product was that for?
A. So to my recollection, there were a number of reasons that I might have attended an Ethicon training course. Part of that was that I was a fellow of Peter Rosenblatt and he was involved in those trainings and so I accompanied him or went along with him.
Some of those things were opportunities to further the technique that I was already learning in the course of my training, whether that was a retropubic sling or a transobturator sling, which is I think the thing I most often remember.
I was able to do that on cadavers which is a completely different experience than performing it on a patient. And so while I did not learn or perfect my technique, I think understanding anatomy is a lot wiser to do on a cadaver specimen than it is on a sleeping patient. So those were opportunities to -- for further education. They weren't what helped me learn to do the procedures. It's also

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possible that I attended a cadaver lab as -- regarding a Prolift or one of the other mesh implantation devices.
Q. And you were a big Prolift user, right?
MR. RUMANEK: Object to the form.
THE WITNESS: I'm not sure what "big" means, but no, I wouldn't say that I was a big Prolift user.
BY MS. WHITE:
Q. When was the last time that you surgically implanted a Prolift device in a patient?
A. Wow. So -- I probably did a few of them after I began my position at Massachusetts General Hospital which would have been in 2006, I believe, so probably over the course of a year or two at Mass General, I may have done five to ten of them.
Q. Okay.
A. Maybe -- probably more on the order of five.
Q. All right. Let's go back to TVT. Please tell the jury when you were first trained to surgically implant TVT in a patient for stress urinary incontinence. When did you first get trained to do that?
A. So I think that training is something that

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happens as a gradual process. So first trained is probably -- that makes it sound as though or I would assume that something where you have this experience and then you go do it, and that's never the case in surgical training. Surgical training is a long process, happening over the course of years.
And so I would say that I was first trained to do such a procedure during my fellowship, beginning from the first time Ethicon products were used probably during the first year of my fellowship and until the conclusion of my fellowship. So over three years I was first trained to do this procedure.
Q. Okay. When's the first time, Doctor, you recall, using the TVT device.
A. I don't think I have a first recollection.
Q. Okay. Fair enough. And so you're going to stick to that. You don't recall when you first remember using the TVT device?
MR. RUMANEK: Object to the form. Asked and answered.
THE WITNESS: I don't think I could identify a time when I wasn't. You know, it's like asking me when I first did a cesarean section. I've done them through my training. I don't remember the first time, but I do know

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that over the course of several years, I learned to do it.
BY MS. WHITE:
Q. Okay. Who trained you to surgically implant the TVT device in a woman for the treatment of stress urinary incontinence?
MR. RUMANEK: Object to the form.
THE WITNESS: So I've had many educators, trainers, teachers over the years. Peter Rosenblatt was certainly a great part of that. Tony DiScuillo, who was another physician at my fellowship, was certainly a part of that. May Wakamatsu, with whom I trained at Massachusetts General Hospital, was a part of that. Joan Bengtson, who was at Brigham and Women's Hospital, was certainly a part of that.
BY MS. WHITE:
Q. Is it fair to say, and I think this is what you've testified to, you first received training on the TVT during those fellowship years?
MR. RUMANEK: Object to the form.
THE WITNESS: Yes, that's fair to say.
BY MS. WHITE:
Q. Okay. How about TVT-O? Okay? When were you first trained to use the TVT-O device?

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A. During my fellowship.
Q. Okay. Did you receive any training on the surgical implantation of the TVT device from Ethicon directly?
A. Not to my recollection. I believe that -- and I guess it really depends on what you mean by "directly." I spent most of my time as a surgical trainee in the operating room -- all my time as a surgical trainee in the operating room with other attending physicians who were primarily responsible for my training.
You know, Peter Rosenblatt worked with Ethicon. And so as he -- as much as he taught me to do that, you know, I've had some exposure to Ethicon in the process. But I would never say that I was directly trained to do the TVT by Ethicon.
Q. Okay.
A. TVT-O, I mean.
Q. TVT or TVT-O?
A. TVT-O is what you asked me about, I think.
Q. No, I asked you about TVT, but let's talk about TVT-O.
MR. RUMANEK: I think she said both.
THE WITNESS: Right. I said both.

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BY MS. WHITE:
Q. Okay. So it's your testimony that you did not receive direct training from Ethicon for the surgical implantation of TVT or TVT-O?
MR. RUMANEK: Object to the form. Asked and answered.
BY MS. WHITE:
Q. I just -- I'm trying to pin down your testimony. It's usually not this hard, but I'm sorry. Just did you receive direct training from Ethicon?
MR. RUMANEK: So she's already -- she answered that question. You can answer it again.
THE WITNESS: One of the reasons that this may be difficult is that I have come to use both TVT and TVT-O through the course of my residency and then fellowship training. So part of that is not any different from learning any other surgical procedure that does or does not involve a medical device. So these are very gradual processes over a long period of time.
And it's not, as I think back over my experience in learning to do these procedures, the question of whether I was trained to do this

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by Ethicon is almost a moot point. I was trained over many years to do the procedure by a broad variety of providers and trainers. And it's a very difficult for me to say, Ethicon trained me to do that because that just wouldn't be accurate.
BY MS. WHITE:
Q. After you left your fellowship and went on to work at Mass General?
A. That's right.
Q. Okay. Did you begin to regularly use TVT and TVT-O to surgically treat stress urinary incontinence in your patients?
A. Yes, I have regularly used TVT and TVT-O.
Q. Okay. So in the course of all these years of training through Rosenblatt, your fellowship, the other folks you mentioned who are also mentioned in your expert report, did you as part of your training rely upon the instructions for use, the IFU?
A. In what manner?
Q. Is that something that also was a basis or a knowledge base for you in terms of using TVT or TVT-O in a patient? Is that something you relied upon and turned to?
A. Not particularly, no.

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Q. Okay. What do you think is the purpose of the IFU?
A. So I believe that the IFU has some purposes. One is to fulfill government requirements for the production of such with the creation of a medical device. And then I think in the case of this particular type of IFU, it's targeted at physicians who are experienced in the treatment of stress urinary incontinence as a discussion and a presentation of the generals of the procedure.
Q. Do you think it's important that the IFU is accurate in the information that's contained therein?
MR. RUMANEK: Object to the form.
THE WITNESS: I think that it is important that the IFU offers accurate information.
BY MS. WHITE:
Q. Okay. Let me ask you this: Are you familiar with a doctor by the name of Vince Lucente?
A. I know a Vince Lucente, yes.
Q. Are you friends with him?
A. Absolutely not. I've met him on maybe one occasion.
Q. Okay. Have you ever attended any of his training sessions for any Ethicon product?

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A. I'm not sure whether it was his training session. It's possible that he was present at a training session that I attended.
Q. But as you sit here today, do you have a recollection of any specific training session on any specific product that you attended with Vince Lucente?
A. No, I couldn't say specifically. I believe he may have been present at one of the Prolift -- or at the Prolift session I think I went to. But I am -- I couldn't tell you where it was or when it was or any more specifics about that.
Q. So you do think that you went to a company-sponsored training program for Prolift?
A. I believe so.
Q. Okay. So let's go back a little bit. During your fellowship years, what were the surgical treatments for stress urinary incontinence involved in your practice?
A. Involved in my training?
Q. Involved in your training. But you're a licensed medical doctor during your fellowship years, right?
A. That's correct.
Q. So 2003 to 2006, you know, what were the

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surgical procedures that you offered patients for stress urinary incontinence?
A. So from 2003 to 2006, the surgical procedures that I offered patients were almost exclusively guided by the advice and input of the physicians that are overseeing my training. So within that context, there were TVT and TVT-O were the equivalent in some other brand so retropubic and transobturator slings.
There were laparoscopic urethropexies, primarily the Burch procedure. There were pubovaginal slings, typically composed of rectus fascia. And there were abdominal or open Burch procedures.
Q. Okay.
A. And also periurethral bulking procedures so Coaptite. Occasionally a collagen injection. And I think that's all.
Q. Okay. So what were some of the other sling products that you used during your fellowship, 2003 to 2006, for -- other than Ethicon products?
A. Hmm. Probably a Bard procedure. I'm not going to remember names. I'm just not good with them, and they never were important to me.
Q. What about the ProteGen sling? Did you

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ever use that?
A. Maybe. The name is familiar to me, but I don't know if that's because I heard it in the literature or in the conversation or because we actually did one.
Q. Are you aware of any complications with the use of the ProteGen sling?
MR. RUMANEK: Object to the form.
THE WITNESS: Not off the top of my head.
BY MS. WHITE:
Q. Were you aware that it was one of the first polypropylene mid-urethral slings pulled off the market?
MR. RUMANEK: Object to the form.
THE WITNESS: No.
BY MS. WHITE:
Q. So other than your reliance upon your fellowship directors, how did you make the decision after you left the fellowship program to start using TVT for the treatment of stress urinary incontinence?
A. So I think it's multifactorial decision. One of the things that is true is that in the greater body of literature, even at that time, TVT was one of the primarily researched slings. And that body of research has almost certainly grown since that time.

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But I felt that it would be prudent to choose a sling about which there is a significant body of literature supporting its use.

In addition to that, at institutions like Mass General, the negotiation and understanding of what's used is part of deciding with your colleagues and partners who also use that even across hospitals which brands will be used and what we kept on the shelf. So I was actually happy to note that those were the ones that were there.

Q. You were happy to note that?

A. I was.

Q. And why is that?

A. Because, again, my exposure to the literature and my experience and training led me to understand that I felt comfortable performing retropubic slings using those -- and transobturator slings using those techniques, and so I was happy to continue to use those things that I thought were best used in my hands.

Q. Well, back in 2006, after you're done training, you're now at Mass General, what literature specifically were you relying upon that gave you that level of comfort, that made you happy that this was stocked on the shelves?

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MR. RUMANEK: Object to form.

THE WITNESS: So I think it would be hard for me to point to one specific study. I think there, even at that time, were multiple case series dating back many years to follow along patients with retropubic slings, and I think the mass -- the total mass of the literature at that point would probably be part of that.

I mean, we could do a Medline search that ended at 2006 and I can tell you to some degree which ones I looked at if you would like, but I think it would be unfortunate for me to choose only one because there are many.

BY MS. WHITE:

Q. Well, I've only got a few hours with you here today, and you're getting paid $600 an hour as an expert for Ethicon as a general urogyn expert for TVT and TVT-O. So can you recall what literature specifically, if there's one that stands out to you back in 2006, that gave you the comfort level to use TVT in your patient population?

MR. RUMANEK: I'm going to object to the form of the question. Asked and answered and to the commentary and argument with the witness.

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BY MS. WHITE:

Q. You can answer, Doctor.

A. Okay. I think it would be very difficult for me to choose one.

Q. Okay.

A. One of the things about the TVT is that there's so much literature here. It's really -- I think I would be mistaken to choose any one.

Q. Okay. What about TVT-O? What if any specific article, clinical trial, literature, level 1 evidence, did you rely upon to -- that gave you that comfort level to start using TVT-O in your patient population?

MR. RUMANEK: Are you asking just about level 1 or the other things?

BY MS. WHITE:

Q. Just, yeah, any piece of literature. I assumed it would be level 1, but maybe it's not. What -- what other than your training with Rosenblatt did you rely upon, okay, to start using TVT-O in your patient population?

MR. RUMANEK: Object to the form.

THE WITNESS: So I think there a lot of things that lead you to start using something. And I'll also observe that one of the challenges

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with new technology is trying to figure out where and how to utilize it in your practice or if. And so I would say that TVT-O did and does occupy a specific group of patients for my practice. So part of that decision process was reviewing again the accumulating literature at that time and speaking with experts, be that the people who trained me or other people that I met at conferences, and looking at various abstracts and other things that were presented. That was pretty early on in the use of TVT-O, in terms of its introduction and presence in the United States and so forth.

And so I have to say that I think that my use of it was probably very limited at the beginning and has grown within a certain niche over time, but I can't point to a specific article.

BY MS. WHITE:

Q. During your fellowship, do you recall representatives from Ethicon being in the OR when either you or Dr. Rosenblatt surgically implanted TVT or TVT-O in patients?

A. So first of all, I would say that it's probably true that as a trainee, I was never in the

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OR without either Dr. Rosenblatt or another one of the attending physicians overseeing my training.

And secondly, I think that it's certainly possible that there was an Ethicon representative present in the OR at certain points. But I don't recall any specific individuals and I couldn't actually say that the representative was actually from Ethicon. It's even -- it's definitely possible that there was someone there.

Q. You just don't recall?

A. I really don't. I mean, it's not really -- they don't play a major factor in the production of the surgical procedure. And they're certainly not part of the doing of the procedure.

Q. Why are they there?

MR. RUMANEK: Object to the form.

THE WITNESS: Why are they there? You know, I think that, in part, as the person providing either new technology or some form of device, I think they want to ensure that procedures are done without question. If there's any question about the device, about the packaging, about the thing that they're providing, I think they feel responsible to see it through.

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BY MS. WHITE:

Q. Do you get patient permission before you permit a pharmaceutical rep to be in the OR?

MR. RUMANEK: Object to form.

BY MS. WHITE:

Q. During the patient procedure?

A. I would.

Q. Since leaving your fellowship program, have you implanted women with any Ethicon device where an Ethicon representative was in the OR with you?

A. I think the answer to that is probably no. But I wouldn't -- I couldn't say 100 percent, no.

Q. So I want to talk to you a little bit about your J & J relationship. After you got trained on the TVT and TVT-O, and I know your testimony is that was primarily during your fellowship and Dr. Rosenblatt, did you serve as a preceptor or proctor for J & J?

A. I don't think so.

Q. Okay. Have you ever been paid as a preceptor or proctor for J & J?

A. I don't think so. But I would have to say that it's possible that I was paid during my fellowship for some of the things that I may have done. I don't think -- I mean, certainly since I finished, I have no recollection of doing that.

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Q. What are some of the things you may have done during your fellowship that you would have been paid by J & J or Ethicon for?

A. An example of that might have been, and I'm not sure -- I'm thinking of this, and I'm not sure it was specifically J & J, which is why I'm not able to say this absolutely which company this was for. But, for example, in a cadaver lab, when others are being trained in what to do, sometimes there are retractions and those sorts of things, so as a fellow, I would be there and perhaps be compensated to be there to retract or to hold or those sorts of things during the process and maybe to help with sometimes the passage of needles and those sorts of things for new trainees.

Q. All right. Other than possibly during your fellowship and serving as an expert, general expert in the mesh litigation and the case specific expert role you're playing, have you previously worked for Ethicon or J & J as a paid consultant?

A. No.

Q. Have you received education grants from J & J or Ethicon?

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A. Not at Mass General, no, and not here as far as I know, no.

Q. Okay. At Mount Auburn?

A. To my knowledge, there was not an education grant that was specifically from Ethicon. But I will say that as a fellow, the recipient of that would have been the fellowship, not me. Unless there was travel associated, which might have been for one of these kinds of conferences.

Q. Okay. How about any sort of research funding agreement, have you ever entered into one with J & J or Ethicon?

A. No, I haven't.

Q. Do you know whether Ethicon restricted the sale of its TVT or TVT-O device solely to physicians who had undergone an Ethicon training course?

MR. RUMANEK: Object to the form.

THE WITNESS: No, I don't know.

BY MS. WHITE:

Q. In your opinion, should only physicians who have undergone Ethicon training be permitted to surgically implant the TVT?

A. No, I don't think Ethicon training has anything to do with being adequately trained to surgically implant the TVT.

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Q. Then why do you think Ethicon has these training sessions? What's their purpose?
MR. RUMANEK: Object to the form, to the extent you're asking her to testify about Ethicon's purposes.
THE WITNESS: Right. So I don't know what Ethicon's intent is. But I can say that I think there are a number of different types of people who come to providing these kinds of surgical procedures. There are people like myself who came through a training program where there were experienced physicians, surgeons, who were, like based on their own experience, able to thoroughly and adequately train me and others like me to do these procedures.
There are others for whom this procedure became something that even though they did perhaps other procedures for urinary incontinence, this was new to them since entering practice, and so they would require some additional training besides their residency training because this wasn't available then. So there are lots of different reasons and different ways you might come to doing one of these procedures, and I think based on your

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background and the timing of it, you might need some additional training.
BY MS. WHITE:
Q. Have you ever sat on a J & J or Ethicon advisory board?
A. I don't think so, no.
Q. And other than your work as an expert in terms of the mesh litigation, have you ever had a professional contract for work that you entered into with J & J or Ethicon over the course of your career?
MR. RUMANEK: Object to the form.
THE WITNESS: I'm not even sure what that means. I mean, was I -- was I a proctor as a fellow and signed something that said I would be a proctor? Possibly.
BY MS. WHITE:
Q. Did you get paid for being a proctor?
A. I don't know. I mean, I'm not sure. I'm giving an example of something that I would have signed. And I -- that's not how I would have characterized myself, but I think that's certainly something that I might have done as part of the signature process of participating in those things.
Q. Have you ever worked for a consultant or an expert for any other pharmaceutical company other

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than J & J or Ethicon?
A. No.
Q. And we're going to talk a little bit more in detail about this, but tell me about your patent on vaginal suspension procedure. Does -- first of all, does that involve polypropylene mesh?
A. So the patent itself does not specifically involve polypropylene mesh, although polypropylene mesh is certainly one of a variety of things that could be used in the patent. Patent is really about a methodology for providing a suspension of the vagina using the sacrum as a suspension point, and doing that procedure through the vagina as opposed to laparoscopically or abdominally in what's known as a sacrocolpopexy which is usually done through an abdominal approach.
Q. So are you in talks with any pharmaceutical company or medical device company about this patent?
A. No. I mean, not any – not any talks that would have to do with adopting the product or using the product, no.
Q. Have you spoken with J & J or Ethicon about this patent?
A. So the patent has only been present in its

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completed form for about a year. And no, I haven't spoken with them about the patent. And I know that I didn't speak with them before then about it because there was never a nondisclosure agreement or any of those things signed between them.
Q. Okay. So as you sit here today, do you recall any complications that arose with the TVT-O during your fellowship program where you were training under Dr. Rosenblatt?
MR. RUMANEK: Object to the form.
THE WITNESS: I do not.
BY MS. WHITE:
Q. Okay. When you have a complication with a medical device, do you automatically report that to the FDA?
MR. RUMANEK: Object to the form.
THE WITNESS: Do I automatically?
BY MS. WHITE:
Q. Yeah.
A. No, I do not automatically. And I think the other question there is really about what is a complication from a medical device specifically. I mean, there are lots of surgical complications from almost any procedure that are possibly but also maybe not associated with the device itself.

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Q. Okay. Let's --
(Pulliam 4 was marked for identification.)
BY MS. WHITE:
Q. I'm going to hand you what we have marked as Exhibit 4.
MS. WHITE: I brought a copy for you, but I'm sure you've got it, her expert report?
MR. RUMANEK: I've got it. That's fine. Thank you, though. I do appreciate.
BY MS. WHITE:
Q. And, Dr. Pulliam, is that your expert report?
A. Yes, it's my expert report.
MR. RUMANEK: Make sure it's signed. I'm sure it is, but --
BY MS. WHITE:
Q. When did Ethicon first approach you about being a general urogyn expert in the transvaginal mesh litigation?
A. In November or December. I think it was December 2016.
Q. And who approached you?
A. Mr. Rumanek.
Q. Who?

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MR. RUMANEK: I did.
BY MS. WHITE:
Q. Okay. Can you say his name for the record?
A. Eric Rumanek.
Q. Were you aware that some of your colleagues, such as Dr. Rosenblatt, had agreed to serve as an expert for Ethicon prior to you agreeing to do so?
A. I wasn't aware that Dr. Rosenblatt had agreed to be an expert witness for Ethicon, no.
Q. What about Catherine Matthews?
A. No, I was not.
Q. Do you know Kim Kenton?
A. I know who Kim Kenton is. And I was not aware that she was an expert witness when I agreed to do this.
Q. Did you discuss your decision to serve as an expert with any of your colleagues prior to agreeing to do so?
A. No, I did not.
Q. Did you discuss it with your superiors at UNC?
A. I discussed it with Dr. Clarke-Pearson, the chair of my department.

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Q. And what did he have to say about it?
MR. RUMANEK: Object to the form.
THE WITNESS: We discussed it primarily as it concerned my other responsibilities at the institution, and he was supportive.
BY MS. WHITE:
Q. So do you recognize Exhibit 4?
A. I do.
Q. Did you write that report by yourself?
MR. RUMANEK: Object to the form.
THE WITNESS: I wrote this report by myself and submitted it in to counsel.
BY MS. WHITE:
Q. Say that again?
A. I wrote it by myself and submitted it to counsel --
Q. So it's your test- --
A. -- to discuss.
Q. Okay. So it's your testimony that you wrote every word of the report by yourself?
MR. RUMANEK: Object to the form. And I'll instruct the witness not to answer about any drafts that may have been created or discussed with counsel.

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BY MS. WHITE:
Q. I'm not asking about drafts. Did you write every word of the report by yourself?
MR. RUMANEK: Object to the form.
THE WITNESS: So every word in this report is my own.
BY MS. WHITE:
Q. Okay. Did you have any input from counsel from Ethicon?
(Instruction not to answer.)
MR. RUMANEK: Object to the form. I'm going to instruct the witness not to answer the question.
MS. WHITE: That's a perfectly appropriate.
MR. RUMANEK: I'm going to instruct the witness not to answer the question.
MS. WHITE: So to be clear, for the record, you're not permitting her to answer whether or not there was input from counsel from Ethicon?
MR. RUMANEK: Correct.
BY MS. WHITE:
Q. Did you have any input from Ethicon company officials?

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A. No, I did not.
Q. Without telling me what was said, how much time have you spent speaking with Ethicon lawyers about the report?
A. An hour or two.
Q. An hour or two?
A. Uh-huh. I think also that the report and preparation for the deposition -- I mean, I'm assuming that you're talking about the creation of the report. Is that right?
Q. Yes, ma'am.
A. Okay.
Q. In the general reliance list -- let's go ahead and mark that.
MR. RUMANEK: I've got a copy of it as well.
(Pulliam 5 was marked for identification.)
BY MS. WHITE:
Q. Dr. Pulliam, I'm going to hand you Exhibit 5. Did you put together the general reliance list?
A. Counsel put together the general reliance list.
Q. And that was provided to you by counsel?
A. The general reliance list was created by

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counsel based on the content of my expert report and also the information that they provided me before I began to write the expert report.
Q. Okay. You're telling me that this general reliance list was put together by counsel based upon your report?
MR. RUMANEK: Object to the form. Mischaracterizes what she just said.
THE WITNESS: I'm telling you that this general reliance list was created based upon the literature quoted in this report and other documentation that was provided to me.
BY MS. WHITE:
Q. Okay. So how much of the general reliance list did you provide counsel?
MR. RUMANEK: Objection.
BY MS. WHITE:
Q. Did you have any input at all with general reliance list?
MR. RUMANEK: Object to form.
THE WITNESS: I did. I did.
BY MS. WHITE:
Q. Okay. So it's your testimony that you provided them some of the materials that went into what we have marked as Exhibit 5?

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A. Correct.
Q. Okay. And what did you provide them with?
A. So when I created this report, what I did was I used PubMed to write the report and then reviewed and provided citations from the literature that I used at PubMed and then I turned to some of the literature that was provided to me and reviewed it as well. And then all of that was provided for the generation of this report.
Q. Have you reviewed every single document that is contained in Exhibit 5?
A. So I have reviewed to varying degrees of detail most of the documents here.
Q. Okay. And you know this is -- I don't know how many pages. They didn't number it. But including -- let's go to the last page, for example, of Exhibit 5.
A. Uh-huh.
Q. I may be referring to the wrong thing. Let's see. Expert reports?
A. Yeah.
Q. You've reviewed all those expert reports?
MR. RUMANEK: Object to the form.
THE WITNESS: I have probably reviewed many of these, but not -- not in equal detail.

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BY MS. WHITE:
Q. Okay. What are some you've reviewed in more detail? Just point them out to me. Expert reports. Last page of Exhibit 5.
A. So it's a little hard for me to specifically identify these based on the way that they're listed here. I have looked through some by Dr. Blaivas, for example, and those would probably be the ones that I am more familiar with. But I would say that, in general, those weren't the kinds of things that I relied on primarily to formulate my opinions for this report.
Q. What did you primarily rely upon to formulate the opinions for your report?
A. So there is a large body of literature, so large I think that not only is it useful to look at some of the many studies that exist but also to look through some and to focus really more on those portions of literature that summarize some of the stronger studies here. So, for example, Cochrane reviews.
Q. So what did you rely upon most? Your clinical experience, education, background, and training, or a literature review as the basis for your opinions?

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MR. RUMANEK: Object to the form.
THE WITNESS: I think it's really impossible to say most. Over the course of a career, there is familiarity with the literature that is bred right into the development of surgical technique, interaction with colleagues, attending and -- attendance at meetings which, in fact, are really sometimes the first time you encounter the literature. So I think it would be difficult to say one or the other.
BY MS. WHITE:
Q. Okay. I'm going to ask you to try, though. I only have one opportunity to depose you. So I'm trying to figure out the basis for your opinions in this case. Is it more on your clinical experience or is it more on your review of the literature?
MR. RUMANEK: Object to the form. Asked and answered. You don't have to answer it differently other than the way you answered it.
MS. WHITE: Speaking objections are not permitted and you know that. You can answer.
THE WITNESS: I think that all of the things that you've mentioned have contributed to my opinions today.

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BY MS. WHITE:
Q. Okay. I'm going to ask you one more time. So what did you rely on most? Is it your clinical experience or review of the literature in formulating your expert opinions in this matter?
MR. RUMANEK: Object to the form. Object to the form. Asked and answered.
THE WITNESS: It's impossible for me to differentiate those.
BY MS. WHITE:
Q. Okay. So then are you saying it's equal reliance on a literature review as opposed to your clinical experience? I'm just trying to figure it out, Doctor.
MR. RUMANEK: Object to form. Asked and answered.
THE WITNESS: I'm saying it's impossible for me to differentiate those. They're intertwined.
(Pulliam 6 was marked for identification.)
BY MS. WHITE:
Q. So I'm going to hand you Exhibit 6. And do you recognize that document?
A. Yes.
Q. And what is that?

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A. This is additional information reliance list.
Q. And I'll represent to you I only got that two days ago. So the supplemental general reliance list, is that information counsel provided to you or you provided to counsel?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't actually -- I mean, I'm not sure that I can go through each one of these and look up which ones are which to see which is which. I mean, I can tell you that these -- for example, these that are the communications from Ethicon are -- and professional education things are clearly things that counsel provided me. I expect that there are some quotes, some papers here that are things that I provided them.
BY MS. WHITE:
Q. Have you read or reviewed each and every document in supplemental general reliance list which has been marked as Exhibit 6?
MR. RUMANEK: Object to the form.
THE WITNESS: I am familiar with much of this literature and have read in detail some of it.

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BY MS. WHITE:
Q. Okay. That's not my question.
MR. RUMANEK: You may not have understood her question.
THE WITNESS: No, I guess I didn't. Go ahead.
BY MS. WHITE:
Q. Have you reviewed each and every document on Exhibit 6, contained in Exhibit 6?
MR. RUMANEK: I just want to make sure. When she says "document," she doesn't just mean the literature. She means every entry on Exhibit 6. Does that clarify?
THE WITNESS: I understand. I guess I'm thinking only of the papers and studies. I have looked at some of these e-mails and other things and familiarized myself with the content, but they're not usually the kinds of things that I would use in the creation of my expert report because they're not the important things in terms of what the science is behind the studies.
BY MS. WHITE:
Q. Yeah. And I'm trying to figure out the basis of your expert report. We have talked about that some. You said you can't differentiate, right,

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between clinical experience and literature review?
A. Uh-huh.
Q. Okay. Is there anything else that you're relying on to form the basis of your opinions in this litigation?
MR. RUMANEK: Object to the form.
THE WITNESS: So you mean in addition to clinical experience and the literature review?
BY MS. WHITE:
Q. Yes, Doctor.
A. Absolutely. I think there's my training. I think there's my exposure at professional meetings and my interaction with other professionals.
Q. Okay. So I want to talk to you now about your clinical experience. So your first job outside training was as the associate director of urogynecology and pelvic reconstructive surgery at Mass General, right?
A. That's right.
Q. Okay. So from August 2006 through 12 of 2012, let's see here.
A. Go back to my --
Q. Yeah, I've got to go back to it, too. Let's do it this way. From August of 2006 to 12 of 2015, did you implant TVT for the treatment of stress

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urinary incontinence?
A. I did.
Q. Okay. And from August 2006 to 12-2015, did you implant TVT-O for the treatment of stress urinary incontinence?
A. I did.
Q. Okay. Doctor, did we mark your expert report?
A. Yes.
Q. What number is that?
MR. RUMANEK: That's 4.
BY MS. WHITE:
Q. 4. Okay. So -- and you may want to keep this in front of you. In your expert report, you say that you have performed 700 mid-urethral slings over the past ten years, right?
A. That's right, roughly.
Q. And how do you know that you have performed more than 700 mid-urethral slings over the past ten years?
A. So I can look at two things. The most reliable thing I think is to understand how many I do in an average month and then realize the number of months I've been practicing. Right?
Q. Okay. So that's how you came up with the

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number 700?
A. That's it. I can also and have in the past, although I didn't re-perform it because I don't have access to those records at Mass General any longer, I can run a billing record to see how many I performed in that way. That's probably the most reliable way to figure out how many of those I performed.
Q. Okay. I'm asking you how you came up with that number for the expert report that's been submitted in this federal court case.
A. That's math.
Q. Okay. So just so I'm clear, you came up with the number 700 based upon the average number of mid-urethral slings you perform in a month?
A. That's right.
Q. Okay. So on average, how many do you implant in a month?
A. Do you have a calculator?
Q. I don't.
A. Okay. So it's been 12 months times 10 years. 5.8 is the average number.
Q. Have you kept a database of all your clients for the past ten years?
A. I have not.

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Q. Have you in any way -- oh, go ahead.
A. I was going to say, I think keeping that and keeping that outside the confines of the hospital in my office would have not been true to patient confidentiality.
Q. Have you in any other way for the past ten years tracked your patients?
MR. RUMANEK: Object to the form.
THE WITNESS: I'm not sure what you mean by tracking.
BY MS. WHITE:
Q. Well, again, I'm trying to figure out how you came up to 700. And I think it's based upon your thoughts on how many slings you place monthly, right?
A. That's right.
Q. On average? And that's how you came up with that number?
A. Uh-huh.
Q. So is there any other basis for the 700 mid-urethral slings other than what you just testified to?
A. No, there's not.
Q. All right. So based on that 700 number that you put in your expert report for this federal court case --

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A. Yes.
Q. -- how many polypropylene mid-urethral slings did you implant from August of 2006 through December of 2015?
A. So I think what you're asking me is how many have I done since that time and to make that subtraction? Is that what you're asking me?
Q. Yeah, the question is simple. Out of that 700 mid-urethral slings over the past 10 years, how many were polypropylene?
MR. RUMANEK: Object to the form and the characterization of the question. I don't think it's simple.
THE WITNESS: So in addition to polypropylene mesh slings, there would have been slings constructed of rectus fascia. That would have been a small percentage of the slings that I've done over that time frame so probably 20 of them over the last 10 years I've done that were not mesh slings.
BY MS. WHITE:
Q. Okay.
A. So that would leave 680 that would be mesh slings.
Q. How many of those 680 mesh slings were

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Ethicon products?
A. The vast majority.
Q. Well, what other products did you use other than Ethicon?
A. There may have been some Bard products there. And I can't remember the name of the other brand with the nondisposable trocars that we used for a brief time.
Q. Did you use AMS products?
A. I don't think so.
Q. Boston Scientific?
A. I don't think so.
Q. Coloplast?
A. Possibly.
Q. You just don't know?
A. No, I know that the majority of the slings that I've used over this time have been Ethicon slings and that the others were not things we decided to go with as a group.
Q. So out of those 680 mesh polypropylene mesh slings, vast majority being Ethicon, can you please identify for the record which specific Ethicon products you have used?
A. Uh-huh. So TVT -- TVT-R I guess is the designation -- I've used the retropubic sling --

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Q. Yes, ma'am.
A. -- with the portion of the trocar that's got the reusable handle. And TVT-O, TVT Abbrevo. And then since I've been here at the University of North Carolina, TVT Exact has replaced the TVT device.
Q. Okay. Out of the 680 polypropylene mesh mid-urethral slings, a vast majority being Ethicon, I need you to tell me how many are TVT-R.
A. So the TVT-R, probably -- I mean, since I've been here, I've done -- they didn't have the TVT-R here, and I've gone with the Exact. So if -- let's just say for easy math, I did five a month since I've been here, and I do probably three-quarters of my slings as TVT Retropubic or TVT, yeah, retropubic. So let's say three quarters of 680 minus 60. That's 450 roughly.
MR. RUMANEK: Let the record reflect that counsel assisted with a calculator.
BY MS. WHITE:
Q. All right. How many of the 680 involve TVT-O?
A. Can I see your calculator?
Q. Why don't you just keep it, Doctor? I'll be happy to even give you my cell phone if you want,

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a calculator.
A. 680 minus what was the number I just gave you? 450. So roughly 230.
MR. RUMANEK: And you said Exact --
THE WITNESS: I'm sorry. That was TVT-O. Oh, right?
BY MS. WHITE:
Q. No, TVT-O.
A. TVT-O. Okay, I apologize. So I probably started using Abbrevo maybe three or four years ago. So let's say I did 150 TVT-Os and the remainder are Abbrevos so another 180.
Q. You've lost me. Let me rephrase the question.
A. Sure.
Q. I'm not trying to drag this out, God knows, but I need to know how many of the 680 transvaginal polypropylene mesh mid-urethral slings were TVT-O.
A. Probably about 120 of them. That's an estimate.
Q. Okay. How many of the 680 polypropylene mid-urethral slings that you have implanted has been TVT Abbrevo?
A. I guess that leaves 110 as the total

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number if we're doing the math. Is that right?
Q. You need to tell us.
A. Right.
MR. RUMANEK: And she's -- she's doing her best to do the math.
THE WITNESS: I'm doing my best to do math. This is not something that is included in my report, and it's all something that I'm deriving off the top of my head because this is not, again, something I based my general report upon in terms of the specific numbers.
BY MS. WHITE:
Q. Okay. Well, you did tell us in this report you've done 700 mid-urethral slings?
A. That's correct.
Q. So I'm trying to figure out your basis for being an expert --
A. Right.
Q. -- on behalf of Ethicon in support of their products.
A. Sure.
Q. Okay. So how many are TVT Abbrevo?
A. So I believe I said 120. Is that correct?
MR. RUMANEK: So you said 450, was that TVT --

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BY MS. WHITE:
Q. Stop.
A. Can we go back? I think we have had this very confusing conversation here, and I would like to review the numbers.
MR. RUMANEK: I'm not trying to interject. Let's go off the record.
(Off record discussion.)
BY MS. WHITE:
Q. We're going to go back on the record. I'm going to ask you questions. If you can't answer my questions, say "I don't know." Okay?
A. Okay.
Q. All right. So Doctor, you previously testified that out of the 680 polypropylene mid-urethral slings that you have placed, 450 is TVT-R.
A. Okay.
Q. You then testified that 120 has been TVT-O. My question to you is, how many of the 680 have involved TVT Abbrevo?
A. Okay. And somewhere in there, I think I answered a question about Exact as well.
Q. Okay. My question on the table is how many have been TVT Abbrevo?

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A. And so that I can make my estimate complete, I'd like to look back, if it's possible, to hear what my answer was about the TVT Exact.
Q. Sure.
(Whereupon the Court Reporter read the requested testimony.)
BY MS. WHITE:
Q. Doctor, you testified clearly that it's 450 TVT-R.
A. That's right.
Q. And 120 TVT-O.
A. Okay.
Q. If you need to stop and figure it out for Abbrevo, please do. But I need to know how many involve TVT Abbrevo.
MR. RUMANEK: Object to the form and the characterization.
THE WITNESS: Okay. So we have got TVT-R and we have got TVT-O which I've said 450 and 120.
BY MS. WHITE:
Q. Yes, ma'am.
A. Okay. And then I think the -- there are 60 or so that were TVT Exact.
Q. Okay.

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A. Okay? And that would leave 50 that are Abbrevo. So that's, to recap, 450 for TVT-R; 120 for TVT-O; 60 for TVT Exact; and 50 for TVT Abbrevo.
Q. When was the last time you implanted a TVT?
A. The last time I implanted a TVT was in December -- a TVT Retropubic, not the Exact; is that correct?
Q. Yes, ma'am, yes, ma'am.
A. That would be December of 2015.
Q. What Ethicon product do you currently use for the treatment of stress urinary incontinence --
MR. RUMANEK: Object to the form.
BY MS. WHITE:
Q. -- in terms of the mid-urethral sling?
MR. RUMANEK: Object to the form.
THE WITNESS: Retropubic sling?
BY MS. WHITE:
Q. Yes.
A. Okay. For my retropubic sling, I currently use TVT Exact.
Q. Why do you no longer use TVT?
A. Because the TVT Exact was the brand of sling that was available here. I regard it as substantially similar to the TVT that I used in my

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previous place of employment and so moved forward with that.
Q. When was the last time you implanted TVT-O?
A. TVT-O?
Q. Yes, ma'am.
A. It's probably been about three years, possibly four.
Q. Why have you predominantly utilized Ethicon mid-urethral slings during your professional career for the treatment of stress urinary incontinence?
A. So I think we talked about this maybe before. But I think there is a great deal of research, a great deal of evidence that would support the use of them. They are -- it's a product that's been present for a long time. And it's a product that I feel comfortable using. And so from my clinical experience, I've had good results so I continue to use it.
Q. How many of the 680 polypropylene mid-urethral slings that you have placed involved mechanically cut TVT? Let's do it this way. Bad question. I'm going to withdraw that. Okay?
How many of the 450 TVT-R, retropubic,

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have involved mechanically cut TVT?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't know.
BY MS. WHITE:
Q. How many of the 450 TVT-R -- and, again, when I say TVT-R or TVT, we're -- they're synonymous -- have involved laser cut mesh?
MR. RUMANEK: Object to the form.
THE WITNESS: I would say that if I didn't know the answer to the first question, the answer to the second is those remaining. I don't know.
BY MS. WHITE:
Q. Okay. That's fine just to say that. Have you over the past ten years documented whether or not you were implanting a TVT laser cut or a TVT mechanical cut?
A. So the documentation of the specific device is always a matter of medical record. So yes. I mean, it would be documented with every device in as much as the device reflects whether it's laser cut or mechanically cut.
Q. Do you know how many TVT laser cut TVTs you have implanted versus TVT mechanical cut?
MR. RUMANEK: Object to form. Asked and

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answered.
THE WITNESS: I don't know.
BY MS. WHITE:
Q. If the TVT mechanically cut device was taken off the market, it wouldn't affect your ability to offer surgical options to women for the treatment of stress urinary incontinence; is that true?
MR. RUMANEK: Object to form.
THE WITNESS: If the TVT mechanically cut device was taken off the market --
BY MS. WHITE:
Q. Could you still surgically treat women for stress urinary incontinence?
A. Yes.
Q. Do you know, Doctor, whether or not you're implanting mechanical cut versus laser cut?
MR. RUMANEK: Object to form.
THE WITNESS: So the TVT Exacts are laser cut.
BY MS. WHITE:
Q. Okay. So back in the day when you were doing TVT, did you know whether or not you were implanting mechanical cut versus laser cut?
A. I know there was a transition between mechanical cut and laser cut. I couldn't tell you

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the exact date of that, but no. And it wasn't important to me as a transition in terms of the appropriate care of patients or in my outcomes.
MR. RUMANEK: We have been going a while so whenever we get to a stopping point, we can take a little break.
BY MS. WHITE:
Q. Of the 680 patients you've implanted with polypropylene mid-urethral slings, how many have come back to you with complications?
A. Oh. Again, it would be an estimate. But I think probably five to seven.
Q. You mean five to seven patients?
A. That's correct. Part of the reason that it's difficult to estimate is that I think when you're asking me about my own that I implant, I think that's probably the number that's most important there in that question.
Q. That's exactly what I'm asking you about.
A. Okay.
MS. WHITE: All right. We'll take a break.
(A recess transpired from 1:18 p.m. until 1:25 p.m.)

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BY MS. WHITE:
Q. So I want to pick up where we left off. I had asked you of the 7 -- actually of the 680 patients where you surgically implanted a polypropylene mid-urethral sling how many have come back to you with complications. And you said that five to seven patients.
A. Right.
Q. So I need you to break that down for me. Of those five to seven patients, how many have been implanted with TVT?
A. Probably five.
Q. Okay. And of those five, how many have been implanted with TVT mechanical cut?
MR. RUMANEK: Object to the form.
THE WITNESS: As I don't know the number, when the mechanical cut change happened, I'm not able really to say how many so I don't know.
BY MS. WHITE:
Q. Okay. And do you know how many of those five had TVT laser cut?
MR. RUMANEK: Object to the form.
THE WITNESS: As I don't know about the mechanical cut, I also don't know about the laser cut.

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BY MS. WHITE:
Q. Okay. And how many of those patients who came back to you had TVT-O?
A. Three. That's five plus three.
Q. That means eight patients?
A. Five plus two. Sorry. Two. I'm estimating and so two.
Q. Okay. And, Doctor, of those 680 patients you surgically implanted polypropylene mid-urethral sling, you don't know how many experienced complications but went to another doctor; is that fair to say?
MR. RUMANEK: Object to the form.
THE WITNESS: I think that that's fair to say for anyone who does any surgical procedure of any kind.
BY MS. WHITE:
Q. Okay. So if I understand you correctly, you currently treat stress urinary incontinence surgically with it's TVT Exact; is that right?
A. TVT Exact, yes, that's right.
Q. Okay. And what other sort of polypropylene sling?
A. TVT Abbrevo.
Q. Okay. And how else do you treat stress

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urinary incontinence surgically if you don't use a polypropylene sling, either TVT Exact or TVT Abbrevo?
A. The other two things I might consider using under specific circumstances would be a laparoscopic Burch procedure. I could use an open Burch, meaning an abdominal incision, if there was an abdominal incision happening for a different reason.
Q. Okay.
A. I use periurethral Coaptite injections. Periurethral Coaptite injections. And pubovaginal slings using rectus fascia typically.
Q. So -- so what -- let me ask you this: Surgically speaking, what procedure do you most use to treat stress urinary incontinence these days?
A. I most use?
Q. Uh-huh.
A. TVT Exact.
Q. And give me a percentage in real time here -- so hopefully this will be a little bit easier for you -- here at UNC, what percentage of the time when you're surgically treating stress urinary incontinence would you use TVT Exact?
A. I would expect between 95 and 98 percent of the time. Oh, I'm sorry. TVT Exact?
Q. Yeah.

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A. Probably 90 percent of the time.
Q. Okay. And break down the other 10 percent for me.
A. The other 10 percent would be 5 to 7 percent TVT Abbrevo, and the other small percentage, Burch or pubovaginal sling.
Q. So how many times have you surgically removed or explanted TVT from a patient under general anesthesia?
A. So are you referring to my own patients, my own patients in whom I placed mesh slings?
Q. I'm referring to I guess any patient. I mean, if you've got them in the OR and you're operating on them, they're your patient, but maybe someone who's even been referred to you; how many times have you surgically removed or explanted polypropylene -- well, strike that.
How many times have you surgically removed TVT from a patient under general anesthesia?
MR. RUMANEK: Just so the question is clear, do you mean TVT Retropubic?
MS. WHITE: Yes.
MR. RUMANEK: The original?
BY MS. WHITE:
Q. Me and the Doctor have an agreement, TVT

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equals TVT-R, okay?
A. So because I know that my own patients have received TVT, I can use that number, and to say that of the five patients that have come back with problems, probably four of them I have removed that mesh. None of those times to my recollection have they been under general anesthetic. They're all under IV sedation with local anesthetic.
Q. Okay. So you've never removed --
MR. RUMANEK: Hold on.
THE WITNESS: I'm not done yet.
BY MS. WHITE:
Q. Go on, please.
A. I work at a tertiary care center so I'm often referred patients who have had mesh, as you observed; they -- my patients might go to someone else and other people's patients might go to someone else, somewhere else as well. And as I work in a tertiary care center, I often see patients who come in with -- often. I am referred patients, I don't often see them, but when I do, they are patients referred to me from outside sources. And they have had a retropubic sling. It's not always possible for me to say that they were TVT. But, in general, I would say that I can tell more recently if they're a

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TVT because they're blue.
And I have probably worked on, over the course of 10 years, probably 10 or 20 patients who I've removed mesh from from a sling. I'm not sure I can say they're TVT. In fact, I can't. But I would say that about half of them have been under IV sedation so maybe -- maybe 10 over the course of 10 years that have gone under general anesthesia. So 10 patients over the course of 10 years under general anesthesia, but I'm not sure that they're TVT because it's not always provable.
Q. Okay. All right. But you think -- of your own patients?
A. Of my own patients.
Q. Make sure I get your testimony right.
A. Of my own patients.
MR. RUMANEK: Let her ask the question.
BY MS. WHITE:
Q. Of the you said four you've removed mesh from, not under general anesthesia, IV sedation?
A. That's right.
Q. Okay. Of your four patients that you've removed TVT from, did you remove TVT mechanical cut or laser cut?
A. I don't know.

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Q. Okay. Of the approximately ten under general anesthesia, and your testimony is you don't know if it was TVT or not?
A. Right.
Q. So I guess you don't know whether it was TVT laser cut or mechanical cut?
A. I don't know if it was TVT at all, let alone mechanical cut or laser cut.
Q. Okay. So TVT-O now.
A. Okay.
Q. How many TVT-Os have you removed under general anesthesia?
A. So of my own patients, which we have agreed is two, both of them were under IV sedation.
Q. Okay.
A. So zero of my own patients. And, again, same applies here. I don't know if these were TVT products from which I have removed under general anesthesia, but I -- I can think of one patient that was removed TVT-O under general anesthesia or -- or not TVT-O. Transobturator sling. I don't know that it was a TVT-O.
Q. So you don't know if you've ever removed a TVT-O under general anesthesia?
A. It's just not necessary.

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Q. Okay. That's not my question. I'm just asking you, have you removed TVT-O under general anesthesia, and you don't know?
MR. RUMANEK: Object to the form of the question.
THE WITNESS: What I said was of my own patients, I did not, because it was not necessary, remove TVT-O under general anesthesia. Of patients referred to me, there was one that I removed under general anesthesia, but I'm not certain that it was a TVT-O.
BY MS. WHITE:
Q. Okay. Understand. How do you know that you have removed TVT four times under general anesthesia? How do you know that?
MR. RUMANEK: Object to the form. Mischaracterizes testimony.
THE WITNESS: So I am estimating. And I know that the need for general anesthesia when you remove TVT is uncommon.
BY MS. WHITE:
Q. And why is that?
A. Because the mesh erosions that are typical for TVT are underneath the urethra, and this is a common, easily accessible place for mesh erosions. I

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don't mean that the mesh erosion is common. I mean that if you're going to find it, it's typically near the urethra in the vaginal mucosa.

And so, like many other vaginal procedures including the slings themselves, general anesthesia is just not needed. In addition, general anesthesia may or may not have anything to do with the requirements of the surgeon. There are times when general anesthesia is more safe for the patient. And so my knowledge here is an estimate based on my understanding of the number of patients I've experienced and the type of anesthesia.

In all honesty, to me, I prefer not to have patients under general anesthesia. And so if that's possible, that's what I like to do.

Q. Okay. How many times in your career have you cut or trimmed a mesh erosion or extrusion?

MR. RUMANEK: Object to the form.

THE WITNESS: So I think --

BY MS. WHITE:

Q. And let me qualify that. Of a TVT product.

A. Right. So I think one thing to say is that the first thing you said, and perhaps I could have clarified then. When you say "remove" and you

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then say "cut an extrusion," I'm not sure I think about those as separate items.

Q. Okay. That's fine.

A. So I think if you're going to ask me about numbers, it's certainly likely that there's going to be an overlap in those numbers because I don't differentiate those in my mind. And there's not a different code for qualifying those sorts of things.

Q. So then is it your testimony you have done it four times?

A. No.

MR. RUMANEK: Object to the form.

BY MS. WHITE:

Q. So then give me the number of patients where you have implanted TVT that you've then had to go back and either trim or excise the mesh in some way and that patient was not under general anesthesia. That's all I'm trying to get to.

A. Okay. And that's a separate thing from your previous question which was remove.

Q. That's right.

A. Okay. So I think if we're going to call trim, I suspect that's probably another four or five patients.

Q. Another four or five?

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A. Uh-huh. And of that four or five, probably three or four of them are -- three of them let's say are TVT, and two of them are TVT-O or Abbrevo.

Q. Okay. And I don't want to know about Abbrevo.

A. Right.

Q. I need to know about TVT and TVT-O.

A. Okay. I couldn't differentiate between O and Abbrevo, even if you asked me to.

Q. So then you don't know how many is TVT-O?

A. I know that the combination of TVT-O and Abbrevo is probably a two.

Q. Okay. So let's go back because I want the record to be clear and us to understand your testimony. When I asked you how many times you have surgically removed a TVT from a patient under general anesthesia, you told me four. What did -- what was your --

MR. RUMANEK: Object. Sorry. Object to the form. Mischaracterizes her testimony.

BY MS. WHITE:

Q. Did I misstate something, Doctor? I do want to get this right. Because what I'm trying to get to is what is your understanding of remove. I

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want to make sure you and I were talking about the same thing.

A. Let me tell you what my understanding of remove is.

Q. Please.

A. Okay. So there are a lot of different categories of remove, and I think as as we have been discussing, I've probably thought about the broad categories of removal. Sometimes there is a piece of mesh that's probably less than a centimeter in size that is visible and needs to be removed. Sometimes there is something that can be seen that's more extensive than that that needs to be removed. I mean, there's sort of a broad spectrum of those sorts of things. So that's that.

The other would be pieces that are visible that could be excised in the office. And I say this, and I feel like I want to say that I'm describing this large universe of possibilities, but that doesn't imply that there are lots of them. It just implies that there's lots of options for what you -- we might be discussing for removal. Right? So you could remove the whole sling from the entire U shape or hammock shape from a TVT or a TVT-O or you could remove a few fibers underneath the urethra.

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General principle I think is that you would like to remove what's necessary, certainly no less than that and probably no more than that because you want to minimize any other untoward effects of surgery, operative time, et cetera.

Q. Okay. Thank you. So I've got to go back and ask you some questions to clarify your testimony. Let's do it this way. Given I now understand your understanding of remove, how many times have you surgically removed the whole TVT from --

A. The entire TVT?

Q. Yes, ma'am.

A. In a situation in which I knew it was a TVT?

Q. Yes.

A. Never.

Q. Okay. How many times have you removed the whole TVT-O from a patient?

A. Again, when I didn't -- when I was certain it was a TVT product?

Q. Yes.

A. Never.

Q. Okay. So now let's go back and talk about excising or removing or cutting fibers or strings of mesh. How many times have you surgically removed

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under light sedation, no sedation, general anesthesia, I don't care, how many times have you removed TVT from a patient?

A. And just to clarify. We have talked about one extreme which was removing everything.

Q. Yes, ma'am.

A. And now we're talking about what I presume is the other extreme which is removing just a few fibers; is that right?

Q. Yes, ma'am.

A. Okay. So probably there, in which I knew it was a TVT Retropubic?

Q. Yes, ma'am.

A. Probably five times.

Q. Okay. And out of those five times, how many times was it mechanical cut TVT?

A. I don't recall.

Q. And how many times was it laser cut TVT?

A. I don't recall.

Q. Okay. And TVT-O?

A. Uh-huh.

Q. How many times did you just remove a few fibers?

A. Two, three times.

Q. Okay. I think you had previously

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testified --

A. That was before we made the definitions that we have just created, right.

Q. Okay. So your testimony is that two to three times you've removed some part of, not the whole TVT-O?

A. So we talked about fibers.

Q. Right.

A. There is a vast difference between removing everything and removing fibers.

Q. I understand.

A. Okay. So I'm talking about fibers. That's what we agreed upon as the -- as the second category.

Q. Oh, I'm with you. I'm with you. So you're saying your testimony is two to three times, right?

A. That's right, in circumstances where I knew it was a TVT-O.

Q. When was the last time you did a revision, meaning just a few fibers, to a TVT-O?

A. Probably about two years ago. It's -- it's not something that I have a date on that I can pull out of my head.

Q. Okay. And I think we have covered this,

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but I want the record to be clear, have you in your clinical practice ever followed the outcomes of your patients who have had mechanically cut TVT versus laser cut TVT?

MR. RUMANEK: Object to the form.

THE WITNESS: So you're asking me if I keep a list someplace --

BY MS. WHITE:

Q. Yeah.

A. -- of these patients?

Q. Yes, ma'am.

A. And followed them by contacting them on an ongoing basis?

Q. No, just keep track of them clinically. Have you ever either in research, clinical trials, your practice, ever followed the outcomes of your patients who have had mechanical cut TVT versus laser cut TVT?

MR. RUMANEK: Object to form.

THE WITNESS: So have I done a research on my own patients comparing the two? No, I have not.

BY MS. WHITE:

Q. Have you ever or do you now specifically request mechanical cut or laser cut TVT?

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MR. RUMANEK: Object to form.
THE WITNESS: I do not although I use TVT Exact which I know to be laser cut.
BY MS. WHITE:
Q. Okay. Back when you were using TVT prior to coming to UNC, did you specifically request mechanical cut or laser cut TVT?
A. No, I did not because I don't and haven't experienced any clinical difference between the two.
Q. How do you know?
A. Because I know that there's been a changeover. And know that we have used TVT Exact and also Abbrevo, both of which are laser cut, and I see results of my patients in follow-up in the clinic. There's also return of patients who come back if they've had failure. And I just don't see it.
Q. Okay. So, this is very important. Are you saying that TVT Abbrevo, TVT Exact, and TVT Retropubic laser cut and TVT mechanical cut are all equivalent products?
A. I'm saying that the clinical results I see from those products are equivalent in terms of the outcome regarding the stress urinary incontinence.
Q. Well, if it turned out that all five of your patients who you did some type of revision on

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regarding the TVT that you previously testified to, if that all happened to have been laser cut or mechanical cut, would that change your opinion?
MR. RUMANEK: Object to the form.
THE WITNESS: I think it's a supposition to say that that could possibly be the case.
BY MS. WHITE:
Q. But you don't know, do you, Doctor?
MR. RUMANEK: Let her finish her answer.
THE WITNESS: I think that the -- the truth is that mechanically cut and laser cut are -- have also not been shown to have higher rates of erosion or urinary retention or pain or any of the other reasons that I would think about needing to remove a sling so I think it's unreasonable to assume that there would be one or the other.
BY MS. WHITE:
Q. What is the basis for that opinion?
A. The medical literature.
Q. Okay. So you're relying upon the medical literature for that opinion?
A. I am.
Q. Because you haven't tracked it in your career. We have established that, right, this

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morning?
MR. RUMANEK: Object to the form. Mischaracterizes her previous testimony.
THE WITNESS: Even if I did track it in my own career, we have established that I do -- I have done 680 of all such slings during my career, and there are literature which supports from views of thousands and thousands of women. It would be useful for me really to refer to the reviews, to the Cochrane database and other ways of evaluating large cohorts. In general, that's the sort of data that I rely on to make the kinds of decisions about my practice.
BY MS. WHITE:
Q. Okay. Have you ever been provided with documents from Ethicon that show that the mechanically cut TVT can fray?
MR. RUMANEK: Object to the form.
THE WITNESS: So I've seen pictures of mesh provided in this bit of information here, this information that shows mesh that's been pulled on and frayed.
BY MS. WHITE:
Q. I don't think that's what I asked you. I mean, maybe the answer is I don't know. Let me

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rephrase the question.
Have you been provided with documents from Ethicon, meaning Ethicon documents, that show that the mechanically cut TVT can fray?
A. So I think by fraying, you mean that there are small particles of mesh that are released if you pull on a sling? And I've seen that it happens. And I've seen that from Ethicon.
Q. Do you have an opinion as to what causes that?
A. Well, I think undue and unnecessary stress on the sling. I mean, I -- will cause fraying. And that's I think true about laser cut mesh as well as mechanically cut mesh.
Q. Have you been provided documents from Ethicon that show the safety profile of mechanical cut versus laser cut TVT?
A. In what way the safety profile?
Q. That there's a difference?
A. That there's a difference in safety?
Q. Yes.
MR. RUMANEK: Object to the form.
THE WITNESS: What kind of safety?
BY MS. WHITE:
Q. You don't get to ask me questions. I'm

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asking you, have you --
MR. RUMANEK: Hold on just a second. She can ask. If she needs you to clarify the question, she can ask you.
BY MS. WHITE:
Q. Let me rephrase it. Have you been provided documents from Ethicon that show a difference in the safety profile of mechanical cut versus laser cut TVT?
MR. RUMANEK: And I just want to stop for just a second because I don't want what she said to confuse you in any way. If you don't understand something that she asks, you absolutely can ask her questions to clarify it so please disregard what she said. Go ahead.
THE WITNESS: So I have seen documents about the safety profile of mesh. And I have seen documents about the safety profile with regard to things like cytotoxicity, with regard to complications from the surgical procedures.
I don't know that I've seen a direct comparison of laser cut mesh to mechanically cut mesh in any major research study that would be meaningful to me, although I know that they've probably been evaluated on a mechanical basis.

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I think probably those kinds of things were the sorts of things that I reviewed briefly and then passed over in favor of some of the larger reviews of the literature.
BY MS. WHITE:
Q. Have you seen documents that show that mechanically cut TVT can rope?
MR. RUMANEK: Object to the form.
THE WITNESS: So, again, I'm going to assume that roping means that when it's pulled on very hard, it becomes thinner and pulls together? And if that's the case, I have seen documents that show that it can rope.
BY MS. WHITE:
Q. What -- in your opinion, what causes TVT to rope?
MR. RUMANEK: Object to the form.
THE WITNESS: In my opinion, what causes TVT to rope?
BY MS. WHITE:
Q. Yes, ma'am.
A. Are you talking about laser cut or mechanical cut mesh?
Q. I'm not -- I'm talking mechanical cut.
A. Okay. I think unnecessary, undue stress

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on the thing, yanking on it from one end to the other can cause roping.
Q. So is it your opinion that TVT mechanical cut only ropes or curls when there's undue pulling and stretching, meaning undue tension?
MR. RUMANEK: Object to the form.
THE WITNESS: I think that's right. I think left without undue tension, it's likely to lay flat which is how it presents in the box and how it's to be placed.
BY MS. WHITE:
Q. So would that be doctor error in implantation?
MR. RUMANEK: Object to the form.
THE WITNESS: I think it's hard for me to say globally about every individual case in doctor error. But I think that the instructions for use for all of the TVTs would basically suggest that it's to be placed flat and tension free.
BY MS. WHITE:
Q. With no tension?
A. Yeah, with no tension.
(Pulliam 7 was marked for identification.)

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BY MS. WHITE:
Q. All right. I'm going to hand you -- I'm handing you what is Exhibit 7, an IFU?
A. Great.
Q. And are you familiar with Exhibit 7?
A. This looks like the English part of the TVT instructions for use. Yes, I'm familiar. Is that right?
MR. RUMANEK: I was just looking at the year.
MS. WHITE: Let's go off the record for a minute.
(A recess transpired from 1:54 p.m. until 1:58 p.m.)
BY MS. WHITE:
Q. All right. Back on the record. Sorry about that. I am sorry Exhibit 7 is so small. I feel your pain. I really do.
So you just testified that TVT is intended and supposed to be placed in a tension-free manner. Is that right, Doctor?
A. That's right.
Q. Okay. So if you take a look at page 5 of the -- of Exhibit 7. And it's the top bullet. Well, it's second to the top bullet point. And I'm going

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to read it to you.
A. Okay.
Q. Just because I know you're probably having difficulty. It says, "Ensure that the tape is placed" -- wait, wait. Sorry. Back up. Go to page 4. Go to page 4. I'm sorry.
Page 4. And it's under Warnings and Precautions. And it's the third bullet point. And I'm going to try to read this.
And first of all, Doctor, have you seen the IFU before today?
A. I have.
Q. Okay. And have you used the IFU in the course of your practice, you know, since your fellowship through today's date?
MR. RUMANEK: Object to the form.
THE WITNESS: So I don't routinely refer to the IFU.
BY MS. WHITE:
Q. Have you -- did you ever refer to it prior to doing a TVT surgical implant on a patient?
A. If you mean do I read the instructions before I do the procedure? I do not.
Q. No, that's not what I asked. Have you ever -- at some point in your career, did you take

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the time to read Ethicon's IFU?
MR. RUMANEK: Object to the form.
THE WITNESS: Yes. I've read at least portions of it in my career.
BY MS. WHITE:
Q. Okay. And so if you go to page 4, and it's the third bullet point, it says -- I can't read that. Under Warnings and Precautions, "Users should be familiar with surgical technique for bladder neck suspensions and/or should be adequately trained in implanting the GyneCare TVT system before employing the GyneCare TVT device. It is important that the tape be located without tension under the mid-urethra."
Do you see that?
A. I do.
Q. Is that a true statement based upon your clinical experience?
A. So it is true that users should be familiar with the surgical techniques for surgery and adequately trained. And it is true that the tape should be located without tension under the mid-urethra.
Q. Okay. So now, go to page 5. This has been a laborsome exercise. Sorry about that.

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If you go to page 5, and it is the second bullet at the top of page 5. It says, "Ensure that the tape is placed with minimal tension under the mid-urethra."
Do you see that?
A. I do.
Q. Okay. So I guess my question to you is, is it no tension or minimal tension?
A. So in the instructions for use, I think the key thing here is that these are instructions for surgery to surgeons. In general, in surgery, in placing or controlling something, there is what I'll call the gentle approach and then there's the firmer grasp. And in the gentle approach, I can give an example of holding something that may bleed. It's impossible to not hold it perhaps in a surgical scenario, but if it's grasped, it needs to be held under minimal tension which is the same thing as no tension because it will bleed.
So I think that in reading this as a surgeon, I perfectly understand what this is instructing me to do. And I don't -- I don't see any conflict between the two.
Q. So what does the scientific literature tell physicians in terms of whether it should be no

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tension or minimal tension?
MR. RUMANEK: Object to the form.
THE WITNESS: Scientific literature is probably not the place that most people learn to do these, just as the IFU is not the place where surgeons learn to do these. Surgeons have a background in surgical handling of tissues, in the placement of other slings in likelihood besides suburethral slings and in the treatment of all things that have to do with the vagina before they do this. So they have vast experience in doing vaginal surgery.
I don't know that I think the literature, which refers to the appropriate placement of slings, is going to instruct someone in how to do it, at least not in a randomized controlled trial, looking at tensioning as much as it's the surgical training that you have that would lead you to understand how to do this.
BY MS. WHITE:
Q. So is it your testimony that no tension on page 4 is the same as minimal tension on page 5?
A. It's my testimony that these are surgical instructions for surgeons who routinely handle tissue.

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Q. Okay. So based upon your expert opinion, is it acceptable for a physician to place the TVT with minimal tension?
A. It is acceptable for a surgeon to place a TVT in the way that they've been trained to place a TVT such that it does not provide urinary retention and does provide treatment for stress urinary incontinence. And I think the literature would suggest that generally we're very successful in doing that with TVT. The success rates are good. The retention rates are low.
Q. Then what's the problem with placing the TVT with tension?
MR. RUMANEK: Object to the form.
THE WITNESS: So the problem with placing the TVT with tension, and I think we're talking about degrees here, right? I mean, I think when I talk with my patients, I essentially tell them that I am an experienced surgeon. And in every kind of surgical procedure you have, you want someone who knows what they're doing. And I know how to place this sling.
The problem with unnecessary tension is that it causes or may cause, doesn't always cause, but it my cause voiding dysfunction,

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urinary retention.
BY MS. WHITE:
Q. Okay. And that's very painful for a woman when she has urinary retention, right?
MR. RUMANEK: Object to the form.
THE WITNESS: Urinary retention sometimes is physically painful. It's not always physically painful.
BY MS. WHITE:
Q. You don't want that for your patients, right, Doctor?
A. I do not want that for my patients.
Q. Have you seen internal documents from Ethicon reflecting that the mechanically cut TVT can release particles in a woman's body?
MR. RUMANEK: Object to the form.
THE WITNESS: I have seen some documents to that effect, yes.
BY MS. WHITE:
Q. Do you -- what causes that?
MR. RUMANEK: Object to the form.
BY MS. WHITE:
Q. In your expert opinion?
A. So I think that there are probably a variety of things that cause it. I think that the

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technique of mechanical cutting and then perhaps undue tension on it can cause fraying which releases particles. I think that an interesting thing to note about these particles is that they're made of the very same thing as the mesh. And all of that is made of polypropylene. A suture of polypropylene is essentially the same thing as these particles and so the presence of polypropylene has not been shown historically for a long time to be a problem.
Q. What's the basis for your opinion for that?
A. My own experience, the fact that polypropylene sutures have been present in surgery for decades.
Q. So are you equating the TVT and/or TVT-O in the vagina with a polypropylene suture placed either in the abdomen or the vagina? Are you saying that's essentially the same thing?
MR. RUMANEK: Object to the form. Mischaracterizes her testimony.
THE WITNESS: I think that I haven't even referred to the abdomen. But I think that there are vaginally placed polypropylene sutures. They even occupy the same space. In history, there have been Kelly plications. Those have

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been done since the 1950s at least that are made from the same material as a polypropylene mesh. They're made from exactly the same material.
BY MS. WHITE:
Q. Okay. So, again, you're equating a TVT and/or TVT-O polypropylene mid-urethral sling with a polypropylene suture?
MR. RUMANEK: Object to the form. Mischaracterizes her testimony.
THE WITNESS: No, I'm not.
BY MS. WHITE:
Q. Okay. I just want to make sure I understand your testimony. We're talking about mechanically cut TVT releasing particles into the body. And your --
MR. RUMANEK: Let her ask the question.
BY MS. WHITE:
Q. And your opinion is there's not a problem with this. Did I understand that part correctly?
A. So I think into the body suggests to me that -- I'm not sure where that is. What I would say is that polypropylene material in the vagina is small fragments of this mesh -- this fray that is equivalent to the presence of a suture. It's the same type of material in the same place that a suture

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might be placed.
Q. Okay. Have you seen Ethicon documents that show that the Prolene, which is what the TVT is made of, Prolene mesh, that the Prolene that's used in the mechanically cut TVT can degrade?
MR. RUMANEK: Object to the form.
THE WITNESS: I've seen lots of literature discussing whether or not polypropylene can --
MR. RUMANEK: Hold on. I think she asked you about --
BY MS. WHITE:
Q. That's not what I asked you.
A. I'm sorry.
Q. Have you seen Ethicon documents that show that the Prolene that's used in a mechanically cut TVT can degrade?
MR. RUMANEK: Object to the form.
THE WITNESS: I may have reviewed some of those here, but, again, for my opinions, I haven't reviewed those as a way to formulate an opinion about this.
BY MS. WHITE:
Q. Okay. And, again, your opinions have been formulated based upon your review of the literature and your clinical experience, right?

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MR. RUMANEK: Object to the form. And the other things that have been discussed and mentioned in her report.
THE WITNESS: And my discussions at national conferences with other professionals, yes.
BY MS. WHITE:
Q. Okay. So based upon your clinical experience, what is the leading cause of TVT revision surgery?
MR. RUMANEK: Object to the form.
BY MS. WHITE:
Q. Again, based upon your clinical experience.
A. Right. So in my clinical experience, TVT revision, and I suppose we should pause here to talking about revision. And maybe, actually, we should work to define that. So I'll say revision would mean perhaps tightening or loosening of the sling or releasing the sling for some issue that's not due to mesh erosion or some other issue that has to do with exposure of mesh? Is that a definition that you would like or is there something else that you --
Q. It's not, and it's not the question. So

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let me -- that's my fault, not yours. All right?
So what -- what is, based upon your clinical experience, the leading cause of you having to go in, the times that we have already discussed this morning, and -- and excise or take out in whole a TVT product?
MR. RUMANEK: Object to the form.
THE WITNESS: So the leading cause -- of the surgeries that we've discussed, the leading cause is the mesh exposure in the vagina.
BY MS. WHITE:
Q. Mesh erosion?
MR. RUMANEK: Object to the form.
THE WITNESS: Sometimes people say that erosion implies presence in a different organ such as the bladder and bowel which is exceedingly rare. And mesh exposure in the vagina also rare is really what I think is the leading cause of going back to the operating room.
BY MS. WHITE:
Q. All right. So let's talk about that in -- for a minute.
Of the -- I think it was the number of patients that we've previously discussed where you've

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either taken the TVT out in whole or in parts, how many of those patients had mesh erosion?
MR. RUMANEK: Object to the form.
THE WITNESS: So the majority of them have mesh exposure in the vagina. And I will reserve those comments to those patients that had surgery under IV sedation as we discussed previously. Those were -- those were almost exclusively exposure in the vagina.
BY MS. WHITE:
Q. Okay. And I think we testified, please correct me if I'm wrong, four.
A. Okay.
Q. Okay? So when you say the great majority, what do you mean by that? What number?
A. Three.
Q. Okay.
A. But I'm not -- I guess I'm also talking about the other categories of TVT. For all categories of TVT, whether we're talking about the retropubic procedures, the obturator procedures, as I think about those in total, all of those are about mesh exposure, not about any other problem so --
Q. I asked you just about the TVT.
A. Yes, you're right. You're right. So

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still, we'll say four.
Q. Is it three or four?
MR. RUMANEK: Object to the form.
THE WITNESS: Right. So if we said four in general, we will say three of those were for mesh exposure.
BY MS. WHITE:
Q. Okay.
A. Okay.
Q. What was the other one because of?
A. Sometimes there's not exposure, but there's irritation at the site. The tissues thin. So that's sometimes another reason to remove if we can't address that in any other way.
Q. Okay. And you testified earlier you have never removed a TVT-O in whole that you know of?
A. That's right.
Q. All right. Okay. And I think you've done two or three --
A. Right. All of these numbers that I've given you are estimates and so I'm -- you're holding me to these firm numbers when I'm adding another estimate, and I think the total number we're going to have to decide is perhaps give or take a few because the first ones were estimates.

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Q. Well, you're an expert in this case.
A. I am.
Q. And I'm entitled to discover your clinical experience.
A. That's fine.
Q. And you've already testified your clinical experience is the basis, at least in part --
A. That's right.
Q. -- of your opinion?
A. Right.
Q. So in fairness to me, you know, you've testified. I've let you explain your answers as much as you want to. So you testified earlier that you've never removed a TVT-O in whole?
A. That's correct.
Q. And that you've done a revision, meaning clipped the fibers, two or three times, right?
A. So I don't think we used the word "revision" previously, but, yes, I've removed fibers two or three times, yes, that's right.
Q. Okay. And was that because there was exposure into the vagina?
A. That's correct.
Q. Okay. So what -- what are in your opinion the pros of the TVT, meaning the TVT-R, for a

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patient? Why did you like that product?
MR. RUMANEK: Object to the form.
THE WITNESS: So I think that there are pros to retropubic slings which includes the TVT-R. And they are to some degree in contrast to other options for patients who have stress urinary incontinence.
But, in general, the TVT-R is -- can be done under local anesthetic with IV sedation. It's a brief procedure, just focusing on the operative -- perioperative advantages. It's a safe procedure. It's an effective procedure. It's a procedure with limited complications, and it's a procedure that is not generally difficult to recover from.
BY MS. WHITE:
Q. Okay. What are the cons of a TVT procedure?
MR. RUMANEK: Object to the form.
THE WITNESS: So I think that, in general, it is always preferable not to have surgery. And that's certainly true of TVT as well as any other surgical procedure for urinary incontinence. I think that it is -- if you're talking about things that are unique to TVT, I

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suspect that the complication rates related to mesh are the only specific, unique thing that I can think of that is not common to all other procedures for urinary incontinence so I guess I would have to name that one. But, in general, that's the con, and that's a very low risk. So it's not much of a con.
BY MS. WHITE:
Q. So what about TVT-O? What are the pros of the TVT-O?
MR. RUMANEK: Object to the form.
THE WITNESS: I would say they're similar.
BY MS. WHITE:
Q. What are the cons?
MR. RUMANEK: Object to the form.
THE WITNESS: I would say that they're similar.
BY MS. WHITE:
Q. Similar to the TVT?
A. That's correct.
Q. Okay. Have you ever looked at pathology from an explanted TVT sling?
A. I have seen photographs and micrographs of those.
Q. Okay. So we'll get to that.

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A. Okay.
Q. But have you ever -- not photographs. Have you ever seen the actual pathology on a slide from an explanted TVT sling?
MR. RUMANEK: Object to the form.
THE WITNESS: So pretty rarely are slings or anything ever looked at with my eyes to the microscope.
BY MS. WHITE:
Q. Yes, that's what I'm --
A. I think putting my eyes to the microscope or putting anyone's eyes to the microscope is not a common way to look at pathology per se. I think most things are actually projected on screen. But, no, I've never looked through a microscope to explanted mesh.
MR. RUMANEK: Make sure to keep your voice up.
THE WITNESS: I'm sorry. I might need a --
BY MS. WHITE:
Q. In those times where --
MR. RUMANEK: Hold on. You need to take like a five-minute break?
THE WITNESS: I need to get up and get a

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glass of water.
MS. WHITE: Oh, sure. Let's take a break. I'm sorry.
(A recess transpired from 2:19 p.m. until 2:22 p.m.)
BY MS. WHITE:
Q. In those times where you've removed mesh from women, specifically TVT, did you request any particular analysis of the explanted mesh?
A. No, I did not. I routinely send it for macroscopic evaluation, just to basically affirm that I've identified and removed mesh.
Q. Do you know what a macrophage is?
A. Yes.
Q. What is a macrophage?
A. It's a cell of inflammation and healing. It's part of the immune system.
Q. And do you know how to identify a macrophage on a pathology slide?
A. I do.
Q. And did you learn that during your pathology internship?
A. Uh-huh.
MR. RUMANEK: You got to say yes.
THE WITNESS: Oh, I'm sorry. Yes, I did.

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BY MS. WHITE:
Q. So when was the last time you looked at a histopathology slide involving explanted Prolene mesh?
MR. RUMANEK: Object to the form.
THE WITNESS: You mean when was the last time I looked at an explanted pathology slide under the microscope?
BY MS. WHITE:
Q. Yes, ma'am.
A. I think, as I mentioned previously, I don't believe I've ever actually looked at that under a microscope, physically.
Q. How many histopathology slides involving an explant mechanical cut TVT sling have you looked at?
MR. RUMANEK: Object to the form.
THE WITNESS: As I said previously, I have not looked at them under the microscope.
BY MS. WHITE:
Q. How many histopathology slides involving an explanted laser cut TVT sling have you looked at?
MR. RUMANEK: Object to the form.
THE WITNESS: I have not looked at them through the microscope.

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BY MS. WHITE:
Q. How many histopathology slides involving an explanted TVT-O sling have you looked at?
MR. RUMANEK: Object to the form.
THE WITNESS: I have not looked at them under the microscope.
BY MS. WHITE:
Q. Have you ever made a histopathologic slide related to a polypropylene mesh after removal from a woman's body?
MR. RUMANEK: Object to the form.
THE WITNESS: The making of a histopathologic slide is not something that's done by a pathologist or a gynecologist. It's an automated function that involves wax and a special machine, and it's usually done as a process in a pathology lab. So no, I have not.
BY MS. WHITE:
Q. Do you know how to make a slide from a mesh explant?
A. I know how to make a pathology slide.
Q. Can you explain to process to me?
A. Sure.
Q. Go ahead.
A. All right. There are variations in the

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process depending upon the materials. But an H&E pathology slide involves first fixing the specimen in formalin and then processing it through a machine that embeds the processing tissue into a piece that's large enough to fit onto -- small enough to fit onto a pathology slide. And placing that in paraffin. And then slicing it onto a microtome so it's placed onto your slide. And then putting a cap on top of it to protect it.

Q. Okay. That's it?

A. For an H&E slide, that's correct. There are different bits of processing, and I understand there's actually a lot of discussion in this area for creating a slide depending upon how you want to clean the mesh, and those are not processes that I have experience with.

Q. Do you believe in the value of histopathology in relation to mesh?

MR. RUMANEK: Object to the form of the question.

BY MS. WHITE:

Q. Meaning what value is it to you as a physician treating women with polypropylene mesh products? Can it tell you anything about what went wrong?

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MR. RUMANEK: Object to the form of the question.

THE WITNESS: So there are a variety of reasons to look at something from pathology. And there are a variety of ways to look at something under many different types of microscopes with many different types of stains and evaluations and cleaning. Within that, in my experience, I haven't performed those for mesh erosions nor have I seen an indication to do so.

BY MS. WHITE:

Q. Can it assist you in determining whether the TVT or TVT-O degraded inside a patient's body?

MR. RUMANEK: Object to the form.

THE WITNESS: I'm sorry? I didn't understand the first part of your question.

BY MS. WHITE:

Q. So can histopathology assist you in determining whether a TVT or a TVT-O degraded inside your patient's body?

MR. RUMANEK: Object to the form.

THE WITNESS: I'm not sure that there's any clear correlation between clinical findings and any even intimation of degradation. I think

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that degradation is certainly something that the -- is a discussion in the medical literature in terms of what happens to polypropylene, and I've read a great deal of literature on both sides of that, but I don't have any indication that whatever degradation may or may not happen has any clinical impact.

BY MS. WHITE:

Q. Okay. Do you believe that a patient can have a foreign body reaction to polypropylene mesh?

A. So foreign body reactions, there are lots of different meanings to that. I think, you know, within medicine, there are lots of different kinds of implants. I mean, ranging from hip replacements to breast implants to mesh. And every time you place something, even a suture that stays, there is a reaction by the body because there's material there that's foreign. I'm not sure that implies pathology as much as it does the normal way in which the body responds.

Q. Give me your definition of foreign body reaction.

A. I think it's an inflammatory initial process that pertains to the body identification and processing of material that's identified by the body

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as not the body.

Q. Okay. Well, can a patient receiving a TVT have an inflammatory reaction?

A. I think inflammation is a normal response to any kind of surgery with or without an implant.

Q. Okay.

A. In other words -- I'll just add this in -- if I make an incision and it heals, inflammation is part of how the body heals.

Q. Okay. Have you ever authored or published any peer-reviewed articles on degradation of polypropylene mesh?

A. I have not.

Q. Have you ever spoke on that issue at any conference?

A. I have not.

Q. Have you ever at any conference lectured, spoke about, presented posters on the use of histopathology of mesh in making clinical determinations for your patients?

MR. RUMANEK: Object to the form.

THE WITNESS: I don't think I have, no.

BY MS. WHITE:

Q. And are you holding yourself out to be an expert in pathology?

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MR. RUMANEK: Object to the form.
THE WITNESS: I'm an expert in pathology as it pertains to the clinical care of my patients.
BY MS. WHITE:
Q. What does that mean?
A. What that means is that I understand how pathologic findings as reported to me or as found under a microscope or in gross description impact the care of my patients. I'm able to make clinical decisions accordingly.
Q. How have you used pathology in making decisions about the clinical care of your mesh patients?
A. So most of my experience with mesh patients has been removing mesh from this exposure that we've discussed. Sometimes there is atrophy meaning thinning of the vaginal tissue that results as a process after menopause. And that is something that is certainly something that I can find on pathology that would prompt me to provide vaginal estrogen to stimulate tissue growth there. That's appropriate. Having said that, I think that microscopic pathology is rarely useful in the treatment of mesh patients.

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Q. Keep your voice up. I can barely hear you.
A. The air conditioner just came on, didn't it? Okay.
Q. So after you remove mesh from your patients, and I know it's only happened five to seven times.
A. Five to seven times in the patients that I know had TVT removed?
Q. That's right.
A. That's right.
Q. TVT or TVT-O?
A. For that I know had TVT removed, that's right.
Q. Do you check to see if there has been a foreign body reaction in that patient to the mesh?
MR. RUMANEK: Object to the form.
THE WITNESS: No, I don't.
BY MS. WHITE:
Q. Do you believe you can see the foreign body response on a histological slide?
MR. RUMANEK: Object to the form.
THE WITNESS: So I think it doesn't matter whether there's a foreign body response. As we have discussed, I think that foreign body

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response is, in general, a typical body response to the presence of something that's not supposed to be there. So I'm not sure it implies pathology. And I'm not sure it has any special significance when removing mesh.
BY MS. WHITE:
Q. Okay. So in your clinical experience, what types of complications have your patients experienced with TVT? Let's start with just TVT based upon your experience with the product since your fellowship, what types of complications have your patients experienced?
A. My patients have experienced, as we've discussed, mesh exposure in the vagina. They have experienced urinary retention. And I would say "they," I don't mean every single one of them. I mean a select few. They've experienced retropubic hematoma.
And I guess I want to emphasize again that I do mostly TVT, but none of these complications are necessarily unique to TVT. I could say the same if you asked me about my patients who had surgical treatment for urinary incontinence.
Q. But, Doctor, I'm asking you about TVT?
A. Right.

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Q. So, please, my question was --
A. Do you want me to talk about things that are unique to TVT or do you want me to talk about all sorts of procedures that occur after treatment for urinary incontinence?
Q. No, I just want you to answer my question. In your clinical experience, what types of complications have your patients experienced with TVT?
A. Okay. So I think that answers my question -- your question.
Q. Mesh exposure in the vagina, urinary retention, and retropubic hematoma?
A. And the one further might be voiding dysfunction, urinary urgency and frequency.
Q. In your clinical experience, what types of complications have your patients experienced with TVT-O?
A. I think all of those things I just mentioned. So urinary retention, voiding dysfunction. I've not had a retropubic hematoma with the TVT-O. And transient thigh pain.
Q. Transient thigh pain?
A. Yes.
Q. Have you ever had any of your patients

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experience ongoing or chronic thigh pain?
A. So if by chronic, you mean longer than a typical six- or twelve-week post-operative period, no, I have not.
Q. Have you ever had a patient have a thigh abscess?
A. No.
Q. Okay. Would you agree with me that TVT has been associated with the following complications; and this is either based on your clinical experience or your review of all the literature you brought here with you today. Okay? So I'm going to go down the list.
A. Okay.
Q. Mesh erosion into the urethra?
A. Yes.
Q. Mesh erosion into the vagina?
A. Exposure, as we talked about, yes.
Q. Pain a year or more after surgery meaning chronic pain with TVT?
MR. RUMANEK: Object to the form. Object to the form.
THE WITNESS: I think that's true and similar to other procedures for urinary incontinence. The other two you mentioned are

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unique to TVT. Or TV- -- or to mesh slings.
BY MS. WHITE:
Q. Do you agree with me that there's a difference between post-operative pain and chronic pain?
A. In general, yes, I do.
Q. Okay. How do you distinguish between the two?
A. So every patient is different. And by that, I mean, I think that it's unreasonable to expect that the rate of resolution of pain after surgery occurs at the same rate for every single patient. But, in general, I would say that chronic pain could probably be expected to be diagnosed after about six months postoperatively. I think that's not a firm number. There are certainly patients who come into surgery with either a predisposition towards pain or existing pain that can be exacerbated, and those things are harder to address.
Q. In your opinion, can chronic pain from TVT develop more than six months after implantation?
MR. RUMANEK: Object to the form.
THE WITNESS: No, not if it wasn't present before six months.

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BY MS. WHITE:
Q. And is that opinion based upon anything you have found in the medical literature?
A. I think that opinion is based upon basically the challenge of attributing. In other words, after six months, especially if there's been no pain, causality there I think is really challenging to establish.
Q. So that's the basis for your opinion?
A. That's right.
Q. You're not citing something in the medical literature?
A. What I'm saying is that I don't think I can find a solid study that would say that research has shown that -- that there is or is not chronic pain that occurs after any surgical procedure after six months. It's just not possible to directly attribute those things in a way that is consistent.
Q. Okay. So would you agree with me that TVT has been associated with painful sex?
MR. RUMANEK: Object to the form.
THE WITNESS: Like other surgical procedures for urinary incontinence, TVT has been associated with painful sex.

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BY MS. WHITE:
Q. Yeah, and I'm not asking about other procedures.
A. I understand.
Q. Just TVT. Urinary retention?
A. Yes, as I said.
Q. Death?
A. I think there have been case reports of death following surgical procedures with TVT.
Q. Do you know of or have -- do you know of either in the literature or have you experienced death after a Burch procedure?
MR. RUMANEK: Object to the form.
THE WITNESS: I'm not familiar with case reports that would identify death after Burch procedure and I have not experienced death after a Burch procedure.
BY MS. WHITE:
Q. And what about in a pubovaginal sling?
MR. RUMANEK: Objection.
THE WITNESS: I'm aware of case reports. I have not reviewed them myself and -- not personally at all.
BY MS. WHITE:
Q. I couldn't hear you. You are aware or not

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aware?
A. I said I am aware of reports. I have spoken with individuals who would verify that.
Q. And who are those individuals? Death after pubovaginal sling?
A. Eman Elkadry.
Q. And how do you spell that person's last name?
A. E-L-K-A-D-R-Y. And I'm not saying that she personally had a death associated with a sling.
Q. Would you agree with me that hemorrhage or hematoma has been associated with TVT sling?
A. Like other retropubic procedures, yes.
Q. And what about UTIs? Would you agree with me that the TVT has been associated with UTIs?
MR. RUMANEK: Object to the form.
THE WITNESS: Like other surgical procedures for urinary incontinence, yes, it has.
BY MS. WHITE:
Q. And what about overactive bladder?
MR. RUMANEK: Object to the form.
THE WITNESS: Like other procedures associated with -- for treatment of stress urinary incontinence, yes, it has.

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BY MS. WHITE:
Q. And what about bleeding issues?
MR. RUMANEK: Object to the form.
THE WITNESS: I'm not sure what bleeding issues mean. That's not really a term I know about.
BY MS. WHITE:
Q. Okay. Bleeding issues would mean that a woman bleeds after implantation with the TVT.
MR. RUMANEK: Object to the form.
THE WITNESS: So I'm going to have to explore that a little bit. If you mean immediate post-operative period surgical bleeding, then like other surgical procedures, there is a possibility of immediate post-operative surgical bleeding.
BY MS. WHITE:
Q. Are you aware of in the literature or based on your clinical experience a woman bleeding more than six weeks after implantation of the TVT?
MR. RUMANEK: Object to the form.
THE WITNESS: So when -- when a surgeon hears the word "bleeding," what that evokes in my mind is volumes of blood coming out of the vagina, in an uncontrollable way that's life

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threatening greater than how many weeks, six weeks did you say again? And I would say the answer to that is no. Is there formulation of granulation tissue which is sometimes a part of difficulty healing that causes blood to be present on a napkin afterwards, there is that finding in all kinds of post-operative procedures with stitches in the vagina including TVT.
BY MS. WHITE:
Q. What about reoccurrence of stress urinary incontinence after implantation with the TVT?
MR. RUMANEK: Object to the form.
THE WITNESS: TVT has about 80 to 90 percent success rate. And the failure rate over time, that's very limited based on long-term longitudinal studies, so yes, there's some associated with recurrence.
BY MS. WHITE:
Q. What is the basis for your opinion that the TVT has 80 to 90 percent success rate?
A. Cochrane review that summarizes the vast majority of randomized control trials that were acceptable -- inclusion criteria for Cochrane review.
Q. So Cochrane review. Which specific one

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and what year?
A. I believe it's -- let me look here. Let me look at my reference in my expert report. Sorry. I'm having a little -- the expert report is right here, isn't it? That's probably the best place to look.
MR. RUMANEK: Page 16 is the --
THE WITNESS: Thank you.
MR. RUMANEK: There's the efficacy section.
MS. WHITE: I object to you telling her -- please don't.
MR. RUMANEK: I'm sorry.
THE WITNESS: There it is. It's number 47. Ford. 2015.
MS. WHITE: Ford 2015.
THE WITNESS: Let me emphasize that's one of several systematic reviews and so I think the range of success is probably somewhat variable in there, but that's one of the -- one of the reviews that's a reliable good summary of a lot of level 1 evidence.
BY MS. WHITE:
Q. What's another good level 1 evidence that you rely upon for your opinions that form the basis

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of your report? Can you name one or two?
MR. RUMANEK: Object to the form.
THE WITNESS: I can review the listing and let you know.
BY MS. WHITE:
Q. Just off the top of your head, I mean, what do you rely upon, Doctor, in forming your opinion?
A. I rely on Cochrane reviews, and I rely on other summaries and reviews of level 1 evidence. But I have to say that I'm not very good with names so that's why I had to look up Ford. I mean, that's the very common one. That's an SGS systematic review that's fairly recent, and the names are just not things I access off the top of my head.
Q. Okay. Vaginal discharge, is that associated with the TVT device?
MR. RUMANEK: Object to the form.
THE WITNESS: I would say the answer there is rarely and not consistently at all, and that's based on my clinical experience because I'm not really aware of systematic reviews that describe vaginal discharge as a separate item.
BY MS. WHITE:
Q. What about permanent nerve damage? Has

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that been a complication associated with the TVT?
MR. RUMANEK: Object to the form.
THE WITNESS: Like other procedures for stress urinary incontinence, permanent nerve damage is a rare, but known complication of those procedures.
BY MS. WHITE:
Q. Is that a yes?
A. That's a yes.
Q. Acute or chronic pain in the groin, has that been an associated complication of the TVT-O?
MR. RUMANEK: Object to the form.
THE WITNESS: Yes.
BY MS. WHITE:
Q. Acute or chronic pain in the leg, is that an associated complication with the TVT-O?
MR. RUMANEK: Object to the form.
THE WITNESS: I think the groin and the leg are the same thing.
BY MS. WHITE:
Q. Is that a yes?
MR. RUMANEK: You can ask her to clarify.
THE WITNESS: Can you clarify? The toe, the foot, the thigh? There's a lots of parts of the leg.

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BY MS. WHITE:
Q. I take the groin to mean the vaginal area and the leg to be more of the upper thigh.
A. So I would say the medial thigh as it's associated with the groin, yes. And that's a nerve distribution question.
Q. Is thigh abscess an associated complication with the TVT-O?
MR. RUMANEK: Object to the form.
THE WITNESS: I believe thigh abscess is a described complication of some TVT-Os, yes.
BY MS. WHITE:
Q. Well, have you seen it in the literature?
A. Yes.
Q. Have you seen it in level 1?
A. I have.
MR. RUMANEK: Object to the form.
BY MS. WHITE:
Q. And for the jury, explain, what is level 1 evidence in the medical community?
A. So level 1 evidence is a randomized controlled trial. What that means is that there is a review -- there's a research study in which patients are randomized. And by that, I mean they're not selected based on any particular patient criteria.

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In other words, they become part of the study due to a set of criteria. And once they become -- once they meet those requirements, they're randomly placed in either one arm is what it's called or the other arm of the study.
And, usually, those arms do different things. There are two kinds of those things. One of which is that in a randomized controlled trial you can be -- having one thing done to you or the other. And another would be a randomized controlled trial in which you have one thing done to you or a placebo thing so that you're not having really anything to do with you on the other side. Those are more common in drug trials.
Q. In your opinion, what randomized controlled trial do you rely upon the most when counseling patients on whether or not to have or not have a TVT product implanted for stress urinary incontinence?
MR. RUMANEK: Object to the form.
THE WITNESS: So I would say that with regard to slings in general and particularly TVTs, there is a preponderance of evidence such that individual randomized control trials aren't even things that I rely upon anymore. I think

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most of the data that I choose to look at is sort of an even higher summary of those trials such that a systematic review which compiles information from many randomized control trials is my better choice for evidence because it involves more patients.

BY MS. WHITE:

Q. Okay. I want to talk to you a little bit about the Burch procedure. And, Doctor, help me with something. Is a Burch colosuspension [sic] and a Burch urethropexy the same thing?

A. So the Burch colposuspension?

Q. Yes, colposuspension.

A. Yes. There are lots of interchangeable terms, and, mostly, we just say "Burch."

Q. Okay. Because I saw in your report, it looks like to me it's used interchangeably --

A. That's right.

Q. -- and I wanted to clarify that. Okay. How many of these procedures have you performed in your career?

A. So we will draw the line at my career when I began practicing independently after my training?

Q. Sure, that's fine. So we're talking 2006-present.

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A. That's right. I would say 20.

Q. When was the last time you performed one abdominally?

A. Abdominally?

Q. Yeah.

A. 2009 or 2010. I don't do a lot of abdominal surgery and so the bulk of my work there is laparoscopic.

Q. When was the last time you performed one laparoscopically?

A. Three months ago.

Q. So it was here at UNC?

A. That's correct.

Q. And why did that particular patient have a laparoscopic Burch colposuspension rather than a mesh implant?

A. It was her preference after counseling.

Q. How many of your patients after counseling choose either a Burch or a pubovaginal sling rather than a mesh implant for treatment of stress urinary incontinence?

MR. RUMANEK: Object to the form.

THE WITNESS: So I think if we look at the patients who go to surgery because a lot of patients after counseling choose nonsurgical

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options for initial treatment of stress urinary incontinence. I think probably less than 5 percent.

BY MS. WHITE:

Q. Right. Because you've only did 20 in your career?

A. Right.

Q. Right?

A. That's right.

Q. What are the complications you have experienced in your clinical practice with a Burch procedure?

A. So there is urinary retention and voiding dysfunction. There is erosion of sutures through either the vaginal wall or the abdomen. The ones I've seen actually are just in the vaginal wall.

MR. RUMANEK: Hold on for a minute. I'm not sure she was finished.

THE WITNESS: I'm not finished. I'm not finished.

There's hematoma which occurs behind the pubic bone.

BY MS. WHITE:

Q. And, again, I'm asking you in your clinical experience.

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A. That's right.

Q. The 20 that you've performed?

A. That's right.

Q. Okay.

A. And there's failure of the surgery to work in the long term.

Q. So you've performed 20. What percentage of the Burch procedure have you had complications?

A. About 5 percent.

Q. 5 percent.

A. Not all of those are unique to one patient. So it's not that -- it's not that one person had one complication and another person had another complication. Some of those occur in the same patient.

Q. Okay. And -- and how do you know you've performed 20 Burch procedures over the course of your career?

MR. RUMANEK: Object to the form.

THE WITNESS: I think, in general, because they're so uncommon that it's pretty much easy for me to recall.

BY MS. WHITE:

Q. Okay. So in this estimated 5 percent complication, was any of that your fault, surgeon

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error?
MR. RUMANEK: Object to the form.
THE WITNESS: I think it's hard to know. I'm not sure that all complications are a result of surgeon error. I think that many complications are a combination of unfortunate events. Some of them have to do with patient predisposition. Some of them have to do in my understanding with aberrant anatomy. That's been my experience in a particular patient who experienced a lot of problems.
BY MS. WHITE:
Q. Tell me about this one patient that you had because you clearly remember her.
A. I do.
Q. So you had one patient who had multiple problems?
A. Uh-huh.
Q. So what all multiple problems did this one patient have?
A. So to my recollection, she had a hematoma, retropubic hematoma. That comes from large vessels that are behind the pubic bone that bleed. Sometimes those vessels can become very large. I mean, they're like varicosities behind the pubic bone.

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And urinary retention, although not prolonged. So for a week or so, I think. It's been a little while since I thought about this patient. And urgency and frequency.
Q. So if you've done 20 procedures and you've had 5 percent with your patients having problems, essentially, you've had one patient have a problem with a Burch procedure?
A. That's right. She had a terrible time.
Q. All right. I gotcha. The patient -- go ahead.
A. That's okay. I think that's right.
Q. The patient where you performed a laparoscopic procedure three months ago, how is she doing?
A. She's doing just fine. She needed a catheter for about ten days afterwards which is not uncommon in my experience with patients. It takes them a little bit longer in my experience to not require catheterization. Most patients who have a sling, for example, are able to go home on the same day or the day after without any form of catheterization, but the Burch patients typically take a little bit longer in my experience.
Q. Okay. So I just want to make sure I

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understand. The issues that you've seen with a Burch in your own clinical experience, that's been urinary retention?
A. Uh-huh.
Q. Erosion of sutures? That's what you said?
A. Yeah.
Q. So this patient had erosion of sutures?
A. She had a suture that was visible in the vagina. The sutures are taken in the vagina as part of the surgery.
Q. She had a hematoma?
A. She did.
Q. And voiding dysfunction which I think was the urinary retention?
A. Urgency and frequency.
Q. Urgency -- okay. Have you ever had a Burch procedure patient have painful sex after the Burch procedure?
MR. RUMANEK: Object to the form.
THE WITNESS: Not that I know of.
BY MS. WHITE:
Q. Erosion other than I guess you -- erosion of the suture into this one lady's --
A. Those are Gore-Tex sutures which are permanent sutures that we use, placed in the

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retropubic space which is essentially the same space as a sling would span.
Q. Okay. What kind of sutures do you use these days? Is it polypropylene or Gore-Tex?
MR. RUMANEK: Object to the form.
THE WITNESS: For what?
BY MS. WHITE:
Q. When -- for like a Burch procedure?
A. Gore-Tex sutures.
Q. Gore-Tex?
A. Uh-huh.
Q. Why don't you use polypropylene suture?
A. So a little bit of suture choice depends upon the approach. When you do a laparoscopic Burch procedure, so my experience and training and the availability of a long enough suture to tie a laparoscopic knot which requires using a device to place it through the laparoscopic needle driver and down into the retropubic space makes Gore-Tex a preferred suture for that type of procedure.
Q. Okay. And I think based upon your testimony, you've never had one of your Burch patients die, right?
A. I have not.
Q. Okay. How many pubovaginal slings,

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meaning the autologous fascial sling, have you performed in your career since 2006?
A. Probably 12.
Q. When was the last time you performed one?
A. About a year and a half ago.
Q. Was it here at UNC?
A. No.
Q. Mass General?
A. Yes.
Q. Okay. And why did this patient have a pubovaginal sling rather than a mesh implant?
A. So I'm not sure I recall that specific patient, indications for. I mean, I think there are a variety of indications that I would use for a pubovaginal sling. Some of them are, again, patient preference if that's what they choose.
On some occasions, there is some need to place the urethra under a little more tension than a tension-free sling would allow. For example, a -- this may have actually been the last one I did. I had a patient who had had pelvic radiation for a rectal cancer so that damages the tissue around the urethra to the extent that the urethra becomes what's known as a lead pipe urethra. In other words, it's stuck open.

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And so in those kinds of circumstances, you want to put some tension on the urethra in order to close it a little bit. So in that circumstance, since these mesh slings need no tension, a rectus fascia sling is a better choice.
Q. Okay.
A. But, also, those slings are essentially equivalent, with the exception of symptomatic results. And so it's not a wrong choice for a patient at any point to have that choice of a sling. It's just not common.
Q. Have you -- in the 12 autologous fascia sling procedures you've performed, have you ever had a patient have suture erosion?
A. No, although I know it's possible.
Q. Have you ever had one of those patients have voiding dysfunction?
A. So when you place a sling under tension and at the bladder neck, you would anticipate that there's possibly some voiding dysfunction. So while I couldn't give you an actual number, yes, I've had patients who have had voiding dysfunction.
Q. How many out of the 12?
A. Six.
Q. 50 percent?

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A. So, again, this is a select patient population, and I've described to you an example of patients that I would provide the sling for. So they are sort of a unique group. And it wouldn't surprise me nor would it be unexpected to have that kind of dysfunction.
Q. Is it -- is part of it your inexperience doing this procedure that caused 50 percent of your patient population to have voiding dysfunction?
MR. RUMANEK: Object to the form. Mischaracterizes her testimony.
THE WITNESS: I would say it's actually because of the unique patient population in which I perform the slings.
BY MS. WHITE:
Q. So is this voiding dysfunction that you're talking about, is this something that's transient on or are you saying 50 percent of your patient population after this procedure went on to have voiding dysfunction? Meaning something that stayed with them forever?
A. So many patients for whom a pubovaginal sling is placed under some tension, which is intentional, have voiding dysfunction, and some of them have that resolve over time. It's a longer

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period of time than sometimes the immediate post-operative period. But in addition, sometimes there's an expectation that physical therapy will be used to adjust the function of the sling.
But, you know, I think, this is in some ways, again, entirely different patient population, entirely different set of expectations. It's pretty uncommon even in that number that I gave you for me to do this for someone who has typical stress incontinence.
Q. Okay. Who in your opinion is the ideal candidate for a TVT?
A. A woman who has leaking with coughing and sneezing, who has no evidence of urinary retention prior to surgery. And that's an isolated sling, right? So who has in my practice exhausted or at least declined nonsurgical options for treatment.
Q. You've actually been interviewed about what you think the ideal candidate is for TVT.
A. Okay.
Q. Do you recall that?
A. I think you'll have to give me more specifics about that. I talk about this often.
Q. So we'll talk about it more. Would -- do you think that or have you stated in the past that

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another candidate would be someone who is not sexually active?
A. For a retropubic sling?
Q. Yeah, for TVT?
A. I couldn't say with some certainty. I mean, you're going to show me this document in a moment, but I would expect that I didn't say that about a retropubic sling.
Q. Okay. Any -- anything else? And I could be mistaken. We'll talk about it.
MS. WHITE: Let's go ahead and mark that.
(Pulliam 8 was marked for identification.)
BY MS. WHITE:
Q. I'm handing you what we have marked as Exhibit 8. Here, Eric.
Have you seen Exhibit 8 before?
A. I have.
Q. Okay. Do you remember giving this interview?
A. I know Rachel Zimmerman, yes, and I remember giving this interview.
Q. And how do you know her?
A. She contacted me. She works for National Public Radio in Boston.
Q. Okay. So how many times have you declined

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to use vaginal mesh as a treatment option?
MR. RUMANEK: Object to the form.
THE WITNESS: Vaginal mesh meaning mesh to use for?
BY MS. WHITE:
Q. Polypropylene mesh.
A. Okay. And in what context? In mesh for a sacrocolpopexy placed abdominally? Mesh for vaginal repair of prolapse or mesh for a sling?
Q. Stress urinary incontinence for a sling.
A. Having clarified that, I still don't know that I can give you an actual percentage time number of patients that I have declined to use mesh for a suburethral sling.
Q. Do you think that transvaginal surgery with mesh was considered a more straightforward procedure for doctors not trained in abdominal surgery?
MR. RUMANEK: Object to the form.
THE WITNESS: I think that's actually my quote from this article.
BY MS. WHITE:
Q. It is. On page 3. Do you stand by that?
A. So this article is really about using mesh for the repair of pelvic organ prolapse, not for

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stress urinary incontinence.
Q. Okay.
A. And I do think that it was probably developed, the vaginal mesh procedures, as an alternative to abdominal procedures. There are lots of reasons for that. But I think, in general, that is something that I would stand by with regard to surgeries for pelvic organ prolapse.
Q. Okay. So let's go back. We were talking about ideal candidate for the TVT.
A. Yes.
Q. Okay? Who is the ideal candidate for TVT-O?
A. So in my practice, two things. One is that we know there's another Cochrane review that also involves Ford, I believe, but I don't think it's primarily by her, that's evaluated TVT-O and TVT, the use -- for use with intrinsic sphincter deficiency which is a more severe kind of urinary incontinence. And TVT-O in that context is a less effective. So they're not an ideal candidate.
But patients who have garden variety, meaning not intrinsic sphincter deficiency, would be reasonable candidates for a TVT-O.
Q. Okay. Have you ever treated a woman with

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an autologous fascial sling who presented more than one year after her surgery with new onset of pain with sex or vaginal pain related to the sling procedure?
MR. RUMANEK: Object to the form.
THE WITNESS: So if you're reading from the article, I'd really like to see that.
BY MS. WHITE:
Q. I'm not reading from the article. I'm done with the article. I'm sorry.
A. Are you finished with the article?
Q. Yes.
A. Okay. Can you say that again?
Q. Yeah. Have you ever treated a woman with an autologous fascial sling who presented more than one year after her surgery with new onset of pain with sex or vaginal pain that was related to the sling procedure?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't know. I think -- as we have discussed, I think attribution is always challenging after six months after a procedure. Having said that, understanding what the sling is, I am not sure that I would be able to say for certain whether that's the case or not. I

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don't generally keep in my memory the specifics on all the patients that I treat.
BY MS. WHITE:
Q. But you understand for the purposes of serving as an expert in this litigation, it's very important for us to understand your clinical experience. Correct?
A. I do.
Q. Okay. And to the best of your recollection, has that ever happened? Have you ever treated a woman with an autologous fascial sling who presented more than one year after her surgery with new onset of pain with sex or vaginal pain?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't recall.
BY MS. WHITE:
Q. Okay. So, Doctor, you understand that the TVT is made of polypropylene mesh, right?
A. Correct.
Q. Okay. So my question to you is, are there different types of polypropylene mesh?
MR. RUMANEK: Object to the form.
THE WITNESS: So do you mean, are there different ways that polypropylene can be used to create mesh? Yes.

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BY MS. WHITE:
Q. Okay. Yeah, just are there different types of it? I mean, not all polypropylene mesh devices are the exact same material?
A. So they're all made of polypropylene.
MR. RUMANEK: Object to the form.
THE WITNESS: I'm sorry.
MR. RUMANEK: Go ahead.
THE WITNESS: They're all made of polypropylene. But they may be woven or knitted at greater or smaller interstices, and so I think there are different types of mesh in that context, but they're all made of the same thing, polypropylene.
BY MS. WHITE:
Q. Do you know what type of polypropylene the Ethicon device is made with?
A. So --
MR. RUMANEK: Object to the form.
THE WITNESS: Polypropylene mesh used in the Ethicon devices are knitted macroporous meshes.
BY MS. WHITE:
Q. Do you know what type of antioxidants or if antioxidants are in the TVT mesh device?

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MR. RUMANEK: Object to the form.
THE WITNESS: The specific types, no, I don't know.
BY MS. WHITE:
Q. Do you know what type of polypropylene the TVT-O mesh device is made from?
MR. RUMANEK: Object to the form.
THE WITNESS: It's also a macroporous knitted mesh.
BY MS. WHITE:
Q. Excuse me?
A. It's a macroporous knitted polypropylene mesh.
Q. And what does "macroporous" mean?
A. Macroporous means that the interstices, the spaces between the knit, are larger in general than 75 microns. This is an important number because it implies that the cells in the body that can move in to promote healing, angiogenesis and prevent infection are able to make it into the space. That's why macroporous is a very important part of meshes that are used.
Q. Do you know whether the Ethicon TVT is made with the same polypropylene that the Boston Scientific Solyx or Obtryx is made of?

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MR. RUMANEK: Object to the form.
THE WITNESS: I didn't evaluate either of those for purposes of this deposition.
BY MS. WHITE:
Q. Do you know whether or not the Boston Scientific products and the Ethicon products are made with the same grade of polypropylene?
MR. RUMANEK: Object to the form.
THE WITNESS: I didn't evaluate the Boston Scientific meshes for the purposes of this deposition.
BY MS. WHITE:
Q. Are you -- I'm sorry. Go ahead.
A. I didn't evaluate those for the purposes of this deposition.
Q. Well, I'm just asking you -- not for purposes of this deposition -- do you know whether or not the Ethicon products and the Boston Scientific products are made with the same grade of polypropylene? Do you know the answer to that question?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't.
BY MS. WHITE:
Q. Okay. Are you a biomaterials expert?

MR. RUMANEK: Object to the form.
THE WITNESS: I think I'm a biomaterials expert to the extent that it's required of me for the purposes of informing my urogynecologic patient care. In other words --
BY MS. WHITE:
Q. What does that mean?
A. What that means is that I need to understand enough about biomaterials to make good choices for patient care.
Q. Okay. Do you know the type of pellets -- polypropylene pellets that make up the Ethicon TVT device?
MR. RUMANEK: Object to the form.
THE WITNESS: There are pellets that are used to make the Ethicon TVT, but those pellets aren't available to me in my patient care.
BY MS. WHITE:
Q. Have you ever examined the pellets that make up the Ethicon TVT device?
MR. RUMANEK: Object to the form.
THE WITNESS: No.
BY MS. WHITE:
Q. Have you ever looked at them under a microscope?

A. The pellets?
Q. Yeah.
A. No.
Q. And, again, I think I asked you about the antioxidants. What antioxidants are added to the polypropylene that make up the TVT device?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't know.
BY MS. WHITE:
Q. What antioxidants are added to the TVT-O polypropylene --
A. I don't know.
Q. -- device? Are you an expert in polymer science?
MR. RUMANEK: Object to the form.
THE WITNESS: Again, I'm only an expert in polymer science as it pertains to the care of my patients.
BY MS. WHITE:
Q. What does that mean?
A. That means that when I review the medical literature, one of the things I want to know is, are the devices that I'm using safe and effective. And do they cause any problems that can be attributable to the type of tissues or items that we're using.

And in my review of the literature, I don't see anything that I'm concerned about with regard to either TVT or TVT-O.
Q. Have you ever personally conducted any bench or laboratory research on polypropylene?
A. No, I have not.
Q. Have you ever done studies on mesh, not using mesh, but the properties of the mesh?
MR. RUMANEK: Object to the form.
THE WITNESS: No, I have not.
BY MS. WHITE:
Q. How many different grades are there of polypropylene?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't know.
BY MS. WHITE:
Q. Can you name even one antioxidant that goes into the TVT device?
MR. RUMANEK: Object to the form. Asked and answered.
THE WITNESS: No, I can't.
BY MS. WHITE:
Q. What about the TVT-O?
MR. RUMANEK: Object to form. Asked and answered.

THE WITNESS: No, I cannot.
BY MS. WHITE:
Q. Have you ever tested different mesh material for the treatment of stress urinary incontinence?
MR. RUMANEK: Object to the form.
THE WITNESS: So I'm not sure what you mean by "test." I have used different mesh materials in my fellowship, had experience with mesh that's been put forth by a variety of different companies made in the form of retropubic slings mostly for the treatment of stress urinary incontinence. And I have experienced those with my patients.
BY MS. WHITE:
Q. You mean you've implanted different types of mesh products in different patients?
A. So I think -- question would be what you mean by "testing." Have I done test tube like experiments with different meshes? No. Have I experienced them clinically? Yes, I have.
Q. Okay. Do you think that the peer-reviewed literature that you brought here with you today establishes that different retropubic polypropylene mid-urethral slings made by different manufacturers

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perform differently?
MR. RUMANEK: Object to the form.
THE WITNESS: Well, I'm not sure that it's exhaustive. In other words, I -- there is not a large body of literature that compares one type of sling to another. I think the one that comes to mind is the use of the Sparc sling which is a top down sling, in contrast to the use of a retropubic sling by TVT. And the data in that case is in favor, at least equivalent, with regard to the Sparc sling and the TVT sling. So I think they have -- in some reviews, the TVT is superior. In some, they're equivalent.
BY MS. WHITE:
Q. Are there differences in the biomechanical properties of the TVT mechanical cut and the TVT laser cut?
MR. RUMANEK: Object to the form.
THE WITNESS: There are.
BY MS. WHITE:
Q. Okay. Can you tell me what they are?
A. So some of them have to do with what happens when they're placed under a great deal of tension in terms of the stretch and the amount of tensile strength it takes to extend them. But under

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physiologic circumstances, there's really not a lot of significant difference. And both of those things are not things that have been borne out in any of the clinical research about either of them. In other words, even if there is difference in the tensile strength or -- actually, it's not the tensile strength. In the requirement for extending the mesh, it's certainly not something that's been clinically significant.
Q. And what's the basis for that opinion?
A. The basis for that opinion are some of the studies that I've seen. But, also, the large amount of literature that's existed before and after the use of the different meshes.
Q. And you're talking about TVT mechanical cut versus laser cut?
A. Uh-huh.
MR. RUMANEK: You've got to answer out loud.
THE WITNESS: Yes. Sorry.
MR. RUMANEK: We've got about 40 minutes left on the clock at least. Do you need a break?
THE WITNESS: Let me go for a little while.

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BY MS. WHITE:
Q. So I forget what exhibit is your report. But I want to ask you --
MR. RUMANEK: 4.
BY MS. WHITE:
Q. Exhibit 4.
A. Okay.
Q. Okay. So on page 2 of your report, second paragraph from the bottom.
A. Yes.
Q. You talk about your clinical research.
A. That's right.
Q. And you've done clinical research on the cost effectiveness of sling versus pelvic floor physical therapy for treatment of stress urinary incontinence?
A. Right.
Q. Can you tell me about that research?
A. So that is as yet unpublished. I've been working with a fellow, who is not yet presept, although it was an abstract at the American Urogyn Society. The design of that was a decision analysis, and, essentially, we looked at what the options were in terms of treatment in terms of costs overall over the long term for a population.

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The way a decision analysis works is that you try to imagine every conceivable sort of branch point of things that do or don't go wrong of things that do or not cost money, of how long it takes, of decisions, changes, all of those things, and then you try to understand under what circumstances is there advantage of one branch over the other.
Q. Has your research concluded that a sling is more cost effective than pelvic floor physical therapy?
MR. RUMANEK: Object to the form.
THE WITNESS: I think it depends upon how you tweak the metrics.
BY MS. WHITE:
Q. Okay. Can you expand upon that?
A. Sure. We'll give an exaggerated example which is probably not true because I don't have those numbers in front of me right here. But let's say, for example, that a sling procedure for some reason is very inexpensive, but physical therapy costs a lot of money. If we're looking only at a cost/benefit analysis, then it would be advantageous to choose the sling. If physical therapy is very inexpensive and slings are very cheap or physical therapy is very inexpensive and slings are very expensive, then it

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would make certain sense to choose physical therapy because a certain number of patients who undergo physical therapy would not require surgery. And, in fact, that's how a practice -- large number of my patients, I urge and counsel to undergo nonsurgical care first before they choose a surgery.

Q. And how much do you charge for the placement of a TVT -- well, TVT Exact now, what does that cost a patient?

MR. RUMANEK: Object to the form.

THE WITNESS: So the cost to the patient depends upon the patient's insurance coverage and the agreed upon reimbursement according to that. I personally am regulated by the charges that are required of me by the University of North Carolina and the negotiations they have made with each individual insurance company. So I'm not even sure I could tell you what that number is.

BY MS. WHITE:

Q. So you don't even know?

A. No.

Q. What it costs a patient to -- to have a TVT Exact device?

A. What I try to do in my practice is care

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that is -- advising patients solely on the clinical needs of the patient. The University of North Carolina and I, as I have taken on that responsibility, have responsibility for the care of the people of North Carolina. And I understand that to be irrespective of their ability to pay. And so we work with patients with insurance and without insurance to ensure coverage.

There's a plan, it's called Charity Care, that the University of North Carolina provides that covers the surgeries for patients who are unable to pay. And I don't receive anything as part of that agreement personally.

Q. When do you expect your research on the cost effectiveness of sling versus pelvic floor therapy to get published?

A. I don't know. I worked on that when I was at Massachusetts General Hospital with a fellow who's there. And I would like it very much if she would finish that. And if not, after about six months or a year, I'll begin to work on it myself.

Q. Okay. And if I understand your testimony here today, either the Burch procedure or pubovaginal sling or mid-urethral slings, they're all within the standard of care for the treatment of stress urinary

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incontinence?

A. They are.

Q. Okay. Do you prefer mesh over the Burch procedure?

MR. RUMANEK: Object to the form.

THE WITNESS: I prefer the procedure that I think is a combination of sort of the best option for the patient in question. And I find that more often than not, that involves a TVT sling.

BY MS. WHITE:

Q. Okay. And why is that?

A. So, in general, in particular with laparoscopic Burch, which has its advantages with small incisions. The other procedures to me and in my hands have longer operative times. They have the greater potential for complications and in some cases longer recovery.

For example, there's an incision for a pubovaginal slings that's got the potential for pain there that's very different I think from vaginal incisions. I think that, in general, slings are as effective for less time for recovery, for less risk than the other procedures.

Q. In your opinion, is the Burch procedure as

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efficacious as the TVT procedure?

MR. RUMANEK: Objection. Object to the form.

THE WITNESS: I think the literature would suggest that that's true. I think that there are additional things to consider with regard to a Burch that aren't problems of a TVT. For example, patients who have Burch procedures are more likely to have anterior vaginal wall prolapse than patients would have TVTs. And so with that increased risk, that's another surgery that's possible for a patient with a Burch that's not necessarily more likely with someone who has a TVT.

BY MS. WHITE:

Q. Do you counsel your patients that mesh erosion is a possible complication of mesh implantation?

A. Absolutely.

Q. And then do you also counsel them if there's mesh erosion, they may have to have an additional procedure?

A. I do.

Q. Okay.

A. I also tell them that the mesh erosion

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rate is very low and in many systematic reviews is between 2 and 3 percent. So 97 percent of patients or so who have slings placed don't require -- don't have that complication and thus will not require that surgery.

Q. What do you tell them about the Burch procedure?

A. I tell them that there is a longer operative time, that they have a risk of needing an additional prolapse repair surgery and that, in many cases, depending upon the type of surgery that I do, it requires a different approach that takes an enormously much -- an increased amount of surgical time.

Q. Did you use Prolift for pelvic organ prolapse?

MR. RUMANEK: Object to the form.

THE WITNESS: I think we spoke earlier about this. And the answer is I have used it. But it -- not commonly.

BY MS. WHITE:

Q. When was the last time you used it?

MR. RUMANEK: Object to the form. Asked and answered.

THE WITNESS: I don't -- 2008 or '9,

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somewhere in there. I don't know specifically.

BY MS. WHITE:

Q. So let's go back to your report.

A. Before you do, is it possible we can take a little break?

Q. Sure.

(A recess transpired from 3:29 p.m. until 3:32 p.m.)

BY MS. WHITE:

Q. All right. So, Doctor, is it your opinion that the safety of the TVT mesh is not affected by whether it's mechanically cut or laser cut?

MR. RUMANEK: Object to the form.

THE WITNESS: Yes, that's my opinion.

BY MS. WHITE:

Q. And the sole basis for your opinion is your review of the literature because you didn't keep track of it in your patient population?

MR. RUMANEK: Object to the form. Mischaracterizes her testimony.

BY MS. WHITE:

Q. I don't think I did, but you can answer certainly.

A. So I think that because I haven't kept track of it doesn't mean that I haven't had clinical

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experience with my patients and their outcomes. And so I would say that it's also based on my clinical experience with my patients.

Q. Okay. Doctor, once again, how many patients that you've implanted TVT with has had laser cut mesh material?

MR. RUMANEK: Object to the form. Asked and answered.

THE WITNESS: So I've said before, that since I've been here at the University of North Carolina, I've used TVT Exact and Abbrevo which I know to be laser cut. So what I would say is I can't give you an estimate of those before then. But I know that at least those have had laser cut mesh. And I know that I have been doing TVT long enough to have some experience with mechanically cut mesh.

BY MS. WHITE:

Q. And to be clear, I am not here to question you about TVT Exact or Abbrevo.

A. Okay.

Q. Okay. How many of your patients have laser cut mesh wherein you placed TVT?

MR. RUMANEK: Object to the form. Asked and answered.

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THE WITNESS: I don't know.

BY MS. WHITE:

Q. Okay. And, Doctor, do you have an opinion on whether or not the TVT is cytotoxic?

A. It's not cytotoxic.

Q. And what's your basis for that opinion?

MR. RUMANEK: Object to the form.

THE WITNESS: Well, there are the reviews that I cited in my expert report and, actually, in addition to that and in this literature are several abstracts looking at -- oh, no, I'm sorry. Those aren't those abstracts -- but cytotoxicity means that cells die. There's necrosis and tissue death around it. And that's just not what we see in 97 percentish of patients, give or take a few percentage points depending on which study you look at. Patients heal and they heal rapidly. So I think there was the idea of cell death as a result of the presence of the sling is really not borne out clinically.

BY MS. WHITE:

Q. In your opinion, can the TVT device erode?

A. So I think we have talked about mesh exposure in the vagina in the past. And I know that

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that can happen. And we have established that that can happen.
In rare occasions, it can erode, and that's the term that's used, a mesh erosion, into other surrounding organs. Usually, the three that are commonly named would be the urethra, the bladder, and the bowel.
Q. Okay.
A. Those are very rare.
Q. So let's turn to -- just a second. Page 25 of your report and the Instructions for Use section?
A. Yes.
Q. So beginning with this -- the section Instructions for Use there in bold to the bottom of the page, did you -- did you draft all this?
A. I did.
Q. Okay. And did you draft the part where you talk about 21 CFR 801.109?
A. It's in quotations, which would imply that it's a quote.
Q. Where did you get that quote from?
A. I looked it up on the FDA device labeling guidance website.
Q. Do you know what CFR stands for?

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A. No, I don't. But I do know what it refers to which are different descriptions of instructions for use. In other words, there are instructions for use that are prepared for devices that don't require experts, and there are instructions for use that do require experts. And in this instance, the TVT device is specifically directed at -- in terms of the people who are to be using it are people who have specifically listed experience in care for patients with urinary incontinence and surgical experience for the treatment of urinary incontinence.
Q. And tell me again where you got this, the FDA website?
A. Yes. In the guidance for labeling.
Q. Okay. And do you have experience with regulatory affairs or product warnings?
MR. RUMANEK: Object to the form.
THE WITNESS: So I'm exposed to product warnings when they become available as a physician. There are new black box warnings and so forth from the FDA and other product warnings that have become available, I've become familiar with.
BY MS. WHITE:
Q. Have you ever served as a regulatory or

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warnings expert in a case?
MR. RUMANEK: Object to the form.
THE WITNESS: No, I have not.
BY MS. WHITE:
Q. Okay. In forming your opinions in this case, did you review the TVT and TVT-O instructions for use?
A. I did.
Q. Because you do a whole section in your report, right?
A. Right.
Q. Called the Instruction for Use. And do you think the instructions for use as prepared by Ethicon for the TVT and TVT-O is adequate?
A. As there are targeted at individuals like me who are surgeons trained in the care of patients with urinary incontinence and for patient -- or surgeons with experience treating urinary incontinence, yes, I do think they're adequate.
Q. Okay. So what's your opinion about the purpose of the IFU?
MR. RUMANEK: Object to the form. Asked and answered.
THE WITNESS: I think they're a reference for surgeons who are performing these things.

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BY MS. WHITE:
Q. And I think you testified earlier that you agree that they should be -- they should contain accurate information, correct?
A. I think they should contain accurate information. But I don't think that surgeons learn to operate from these things.
Q. It's to inform the surgeon about the product, right?
A. Yes.
Q. And the information that's contained therein about the product should be accurate, right?
A. That's correct, but it's not necessarily comprehensive, either. I think that that's really the point of this quote here in that adequate directions of use cannot be prepared because they are based on the assumption that the person using the device has an extensive background and experience that they bring to the OR with them.
Q. Okay. So let's turn to page 27 of your report.
A. Uh-huh.
Q. And under Ethicon Training, there's a paragraph about credentialing?
A. Yes.

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Q. What -- tell me in your opinion what type of doctor should be permitted to implant a TVT or TVT-O device.

MR. RUMANEK: Object to the form.

THE WITNESS: Permitted by whom?

BY MS. WHITE:

Q. I guess a hospital.

A. So I think that's a little bit of a difficult question to answer in part because I think what you're -- the answer is probably something like surgeons who meet the criteria for the hospital credentialing body.

Q. So here at UNC?

A. Right.

Q. Okay. Before you implant a TVT Exact, what kind of credentials do you have to have?

A. So I've been credentialed at the University of North Carolina as a gynecologist, which is part of my board certification and also part of the experience that I presented in the required information that the university had for me when I came here. And I've been credentialed as a urogynecologist.

And in neither case, actually, at the University of North Carolina does that specifically

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say anything about a TVT. I have privileges to treat stress urinary incontinence and other gynecologic procedures similarly, but they base their credentialing not on any specific item related to TVT at all.

Q. Okay. And, in fact, Doctor, you don't have to be -- have the certification female pelvic medicine and reconstructive surgery to be able to surgically implant a patient with a TVT Exact here at UNC?

A. No, you don't.

Q. Okay. So if you go to the last page of your report, and I'm sorry I'm bouncing around. But the last page?

A. The very last page.

Q. The very last page.

A. There's just not much on it.

Q. "The benefits of TVT/TVT-O far outweigh the risks, and thus TVT/TVT-O have become the gold standard for the surgical treatment of female stress urinary incontinence."

Do you see that?

A. Yes.

Q. When did the TVT and TVT-O become the gold standard for the surgical treatment of female stress

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urinary incontinence?

MR. RUMANEK: Object to the form.

THE WITNESS: So I'm not sure that for anything that's considered a gold standard there is a day of decision. I think that those references become true as there is consensus among professionals who provide the service. I think that as more people do it and more data is acquired about it, I think they move into a position as a gold standard when their safety and efficacy is proven, when it is adopted by experts in the field, and when it's successfully and positively compared to other previous and common type of procedures that might be done for the type of diagnosis.

BY MS. WHITE:

Q. Okay. I'm going to just one more time, do you have an opinion as to when the TVT and TVT-O became the gold standard, what year?

MR. RUMANEK: Object to the form.

THE WITNESS: I don't think that's a fair characterization of how something becomes a gold standard.

BY MS. WHITE:

Q. Let me ask you this: Is the Burch

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urethropexy still a gold standard for the surgical treatment of stress urinary incontinence?

A. It's still an acceptable treatment. I think the reference to the gold standard probably, although there's not a medical definition of gold standard that I can think of, is based on the acceptability of providers and its prominence as the safest and most effective given the other things, the operative time, and all the other things being equal, and the most commonly used, and I think it's become as such the standard against which other things are compared.

Q. Okay. What is your basis for the opinion that you wrote in your report, page 30, that the TVT/TVT-O have become the gold standard for the surgical treatment of female stress urinary incontinence?

A. I think it's been stated in the literature many times. I think that's how it was taught to me during my surgical education, and I think that's my experience.

Q. And is it your opinion that the TVT and TVT-O devices and that procedure for stress urinary incontinence is safer and more effective than the Burch urethropexy?

MR. RUMANEK: Object to the form.
THE WITNESS: It's my opinion that TVT and TVT-O are as safe and as effective as either one of those and in many circumstances are more effective.
BY MS. WHITE:
Q. What are those many circumstances more effective?
A. I suppose I shouldn't say many circumstances. What I mean is that in many systematic reviews, they're more effective. And in some cases, that's objective success like a PAD test or some other physician evaluation, and in some cases, that's a systematic assessment or an assessment that's based on patient experience. But I think if you hold the whole thing in balance, based on those reviews, TVT is a product that is equivalent and likely superior than most measurements.
Q. Given you have only done 20 Burch procedures, how are you qualified to offer that opinion, Doctor?
A. I offer my opinion based on the medical literature, on the preponderance of information comparing Burch and TVT in numbers of patients that I would never achieve in my career no matter how many

patients I operated on. So the preponderance of information is really based on systematic reviews, not just the number of patients that I've operated on.
Q. And, Doctor, you testified you've done about 12 pubovaginal sling implantations, right?
A. That's right.
Q. Okay. And I'm going to ask you the same question. Is it your opinion that the TVT and TVT-O is more safe and more effective than the pubovaginal sling procedure?
A. I think it is as effective. And I think that it is in some cases safer, and based on the evidence, again, that there are unique complications to TVT, TVT-O, and pubovaginal slings that make them comparable. But when you look at all other things being equal, operative time, approach, potential complications, those sorts of things, that this is the gold standard.
Q. And, again, please tell this jury, given you've only done 12 over the course of your entire career, how are you qualified to offer that opinion?
A. I base my opinion about that certainly not only on the number of these I've done, but also on the medical literature which, again, evaluates many

more patients than I would ever be able to operate on in the course of my lifetime. I base it on professional opinions of others in addition to myself. So I feel confident that that's enough for me to be able to say that this is my expert opinion.
Q. And you'll agree with me that patients who undergo the Burch procedure or the pubovaginal sling procedure, they don't have the risk of mesh erosion into organs, right?
MR. RUMANEK: Object to the form.
THE WITNESS: That's correct.
BY MS. WHITE:
Q. Okay. And they don't run the risk of thigh abscesses, correct?
MR. RUMANEK: Object to the form.
THE WITNESS: I would not say that they have no risk of thigh abscess, but they have lesser risk of thigh abscess which is also extremely rare in TVT-O.
BY MS. WHITE:
Q. And as far as you know, you don't know of anyone who has ever died of a Burch procedure, correct?
MR. RUMANEK: Object to the form.
THE WITNESS: I personally do not know of

anyone who has died of a Burch procedure.
BY MS. WHITE:
Q. And you know a doctor who knows someone who had a pubovaginal sling patient die, is that your testimony?
MR. RUMANEK: Object to the form.
THE WITNESS: That is my testimony.
BY MS. WHITE:
Q. Would you agree with me that one of the most important things in medicine for patients is that there is neutrality in their physicians, meaning their physician isn't in there pushing a product for a profit?
MR. RUMANEK: Object to the form.
THE WITNESS: I think the most important thing to patients for their physician is that their physician is an advocate for the very best care for the patient.
BY MS. WHITE:
Q. Do you agree that it's important that there is neutrality in clinical studies and that the evidence that's presented in peer-reviewed literature be neutral?
MR. RUMANEK: Object to the form.
THE WITNESS: I think that "neutral" is a

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very difficult word to use with regard to peer-reviewed literature because a properly conducted clinical trial is designed to show differences and so, by definition, isn't neutral. It's going to show a superior product one over the other.

BY MS. WHITE:

Q. Okay. Let's talk more about neutral and what I'm talking about.

A. Okay.

Q. Is it important for authors of peer-reviewed articles to disclose any financial relationships with manufacturers?

MR. RUMANEK: Object to the form.

THE WITNESS: It is important for authors to disclose financial relationships and other relationships such as board membership or other obligations.

BY MS. WHITE:

Q. I mean, is that important for you as a physician when you're reading a peer-reviewed article to understand whether or not the authors have a relationship with a pharmaceutical company or a medical device company?

MR. RUMANEK: Object to the form.

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THE WITNESS: It's important for me to know where funding comes from regardless of its source. And relationships regardless of their relationship.

BY MS. WHITE:

Q. And whenever funding comes into play, would you agree there is at least a potential for bias?

MR. RUMANEK: Object to the form.

THE WITNESS: I think there is potential for bias for anyone who does research and because the goal of a research is publication. And so unless you want to indict the entire medical literature, I think understanding that bias is implicit in research of any kind is probably important.

Having said that, I think that in this massive evidence that's present for TVT and TVT-O, the value is really with the volume that there are all kinds of people who have contributed to the medical literature. And it's been generally consistent.

BY MS. WHITE:

Q. Would you agree with me that when designing a study, it's important that the study

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authors or investigators do not have a financial stake or interest in the outcome of that study?

MR. RUMANEK: Object to the form.

THE WITNESS: I think investigators always have an interest in the outcome of the study.

BY MS. WHITE:

Q. Always?

A. They always do. I mean, it may not be a financial interest, but they have an interest.

Q. Okay. I'm asking you about a financial stake. I asked you a very clear question. Do you want me to repeat it?

A. Please.

Q. Would you agree with me that when designing a study, it is important that the study authors or investigators do not have a financial stake or financial interest in the outcome of that study?

MS. WHITE: Object to the form.

THE WITNESS: Ideally, there would not be a need for any sort of a financial obligation for a study, as a result of study. But funding of studies is a necessary item so I realize that it's probably a necessary part of research, although sometimes people have financial

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obligations or financial influence.

BY MS. WHITE:

Q. There are many studies out there where the designers and investigators do not have a financial stake, do you agree?

A. Yes.

Q. Suppose that you are an investigator for a study regarding a medical device that is funded by a medical device or pharmaceutical company. Should you be paid more if the results of the study come out one way than if the results come out another way?

MR. RUMANEK: Object to the form. Improper hypothetical.

THE WITNESS: No.

MS. WHITE: Let's go off the record.

(A recess transpired from 3:55 p.m. until 3:58 p.m.)

BY MS. WHITE:

Q. Okay. Back on the record.

A. Okay.

Q. Dr. Pulliam. So getting back on the IFU.

A. IFU, okay.

Q. And you really don't need to look at it, but I want to talk a little bit about it. Is it your opinion that an adequate directions for use or

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instructions for use for the TVT and TVT-O cannot be prepared?
MR. RUMANEK: Object to the form.
THE WITNESS: Well, I think what my opinion is, is that, first of all, adequate depends upon who your target audience is. I mean, for example, to explain to me with surgical experience something would require a very different language and terminology and probably a very different degree of explanation than to explain to someone who has little surgical experience or no surgical experience. And I don't think that the target audience is someone with no surgical experience so I think that given that and given the expertise of the people in the audience, it's really difficult to know what adequate means.
BY MS. WHITE:
Q. Okay. And, again, what about the physician who doesn't have your level of experience?
A. Right.
Q. What is Ethicon doing to prevent those doctors from implanting the TVT or TVT-O?
MR. RUMANEK: Object to the form.
THE WITNESS: So two things. One is --

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I'm not sure. I think it would be something that is necessarily the sole, if at all, responsibility of Ethicon. In other words, there are many things that I need to do before I'm allowed to do any surgery, let alone implant anything. I need to be certified by the board specialty in which I've trained which implies that I have done training in medical school. I need to be credentialed by the hospital in which I work so that they are comfortable in my performance. And I need to continue to undergo that kind of review that occurs on a regular basis by morbidity and mortality evaluations and other evaluations of complications or problems.
And so I think -- Ethicon's responsibility is not necessarily part of what I would expect of them. I think those are things also that you would expect out of a professional to decide what's needed to provide training that's going to really allow them to take care of patients.
BY MS. WHITE:
Q. So let's talk a little bit about the Ethicon training. You testified early this morning that you did not attend Ethicon training other than through Dr. Rosenblatt for implantation of the TVT or

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TVT-O; is that correct?
A. That's right, not to my recollection.
Q. Okay. So do you have an opinion or what are your opinions regarding the Ethicon training that you discuss in your report?
A. Where are my --
Q. So let's go to that. Do you see it, Doctor?
A. I do.
Q. What page are you on?
A. I'm on page 27.
Q. So who drafted this portion of your report on Ethicon training?
A. I'm sorry?
Q. Who drafted this portion of your report on Ethicon training?
A. I did.
Q. Okay. And what is your basis for the substance of this report about Ethicon training?
A. I'm not sure I understand the question.
Q. I mean, how do you know anything about Ethicon training for the TVT and TVT-O?
A. So I recall that what I said was that my own training included my fellowship training and the experience I had with the physicians that were part

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of the fellowship. But I think also we discussed the fact that I was present at the trainings, some of them, that may or may not have been Ethicon, but I certainly attended trainings for slings like this. Right?
Q. Okay. But we're talking Ethicon training.
A. Right.
Q. So I want you to tell me what types of Ethicon training was provided for TVT and TVT-O.
A. What types were?
Q. Yeah.
A. So cadaver labs, for example.
Q. And did you ever attend one for TVT or TVT-O?
A. I don't know that I can say whether I happen attended one for TVT or TVT-O. I have attended cadaver labs for slings in the past including things like this. And I have looked at the information provided to me about those -- those teachings. And I have reviewed monographs and other things that have been provided by Ethicon.
Q. Okay. So your opinions regarding the adequacy of Ethicon training on for the TVT and TVT-O is based upon your review of the documents which have been provided to you by Ethicon?

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MR. RUMANEK: Object to the form.
THE WITNESS: So, actually, I don't think I've ever really spoken about the adequacy of it for anything. I think I -- I've said here, actually, that physician training is intended to supplement, and training and knowledge is not a primary source of expertise.
BY MS. WHITE:
Q. Do you have an opinion as to whether or not providing -- training provided by Ethicon was adequate for the TVT and TVT-O?
MR. RUMANEK: Object to the form. Mischaracterizes.
THE WITNESS: So what I would say is that based on the fact that the MAUDE database, which is a broader reporting, also in that Ford/Cochrane review of complications on a national basis, that the complication rate from placing these things, slings, is very low. And I think that might be one actual clinical factor that attests to the adequacy of training of physicians who perform slings.
BY MS. WHITE:
Q. Is it your opinion that the TVT and TVT-O are safe because they come with a tracking lot number

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and because MDR and MAUDE permit the tracking of complications?
MR. RUMANEK: Object to the form.
THE WITNESS: I don't think they are safe because of that. I think that's a very useful thing in terms of understanding complications. But I don't think that makes them safe.
BY MS. WHITE:
Q. What is the basis for your opinion that TVT and TVT-O are safe?
MR. RUMANEK: Object to the form.
THE WITNESS: I think there are lots of bases. I think I have my clinical experience. I think I have the literature. And I think I have the discussions that I've had with professionals other than myself.
BY MS. WHITE:
Q. Okay. Have you ever implanted a patient with an outdated Prolift kit that was dropped off to you by a Ethicon sales rep by the name of Melissa Doyle?
MR. RUMANEK: Object to the form.
THE WITNESS: So I know who Melissa Doyle is. And I don't recall that, but it's certainly possible.

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BY MS. WHITE:
Q. Okay. And what would be the danger of implanting a patient with an out-of-date Prolift kit?
MR. RUMANEK: Object to the form. It assumes facts.
THE WITNESS: Given my recollection of patient outcomes, I don't think there was any danger.
MS. WHITE: Make this an exhibit.
(Pulliam 9 was marked for identification.)
BY MS. WHITE:
Q. Who is Melissa Doyle?
A. Melissa Doyle is an Ethicon rep or was. I don't know if she still is or not.
Q. So I'm handing you what we have marked as Exhibit 9. This is an e-mail it looks like from Marie Egan.
A. Yes.
Q. Who is that?
A. She was in charge of materials and purchasing at Massachusetts General Hospital.
Q. Okay.
MR. RUMANEK: Let me just note we're over five hours now. I'm going to let you finish this line, but be as brief as you can.

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MS. WHITE: I'm almost finished.
BY MS. WHITE:
Q. And this e-mail is from Marie to Melissa. And she says, "Obviously your opportunity is to capture the business." Marie is talking to Melissa, the sales rep. "Even more desirable with Mandy Pulliam on board."
A. Yes.
Q. Do you recall dealing with Melissa in regards to TVT-O and TVT-Secur?
A. Not specifically, no.
Q. What does she mean by the fact that you're on board?
MR. RUMANEK: Object to the form.
THE WITNESS: So it would be hard for me to know exactly what she meant. Although I could make a supposition that when I joined May Wakamatsu at Massachusetts General Hospital, that meant that instead of there being one, there were two physicians and so the opportunity for two physicians to use a product instead of one meant an increased potential for business.
BY MS. WHITE:
Q. Were you aware that Ethicon frequently referred to you as a VIP customer?

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MR. RUMANEK: Object to the form.
THE WITNESS: No, I wasn't aware.
BY MS. WHITE:
Q. Were you aware that Ethicon frequently referred to you as a high volume implanter of their products?
MR. RUMANEK: Object to the form.
THE WITNESS: No, I haven't seen that information.
BY MS. WHITE:
Q. Would it surprise you?
MR. RUMANEK: Object to the form.
THE WITNESS: So because of my association with Peter Rosenblatt and also the fact that I do pretty much exclusively pelvic reconstructive surgery that treats urinary incontinence and pelvic organ prolapse, it would make sense that I was a high volume user of products that are used for pelvic reconstructive surgery and urinary incontinence.
BY MS. WHITE:
Q. And Melissa did her best over the years to make sure you got invited to VIP activities at various AUG functions and stuff like that, right, throughout the years?

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MR. RUMANEK: Object. Object to the form.
THE WITNESS: I don't know if Melissa did her best. I don't know anything about that.
BY MS. WHITE:
Q. I think that's all we have. Thank you, Doctor.
A. Thank you.
EXAMINATION
BY MR. RUMANEK:
Q. All right. I just have a few questions I want to follow up on. Dr. Pulliam, do you recall throughout the course of the deposition you were asked to give estimates for the number of TVTs you implanted, the number of TVT-Os you implanted, the number of TVT Abbrevos and the TVT Exacts. Do you recall those questions?
A. I do.
Q. And were the numbers that you provided in the deposition absolutely hard and fast numbers or were you giving estimates?
A. They were absolutely not hard and fast numbers. They would be estimates, complete estimates.
Q. Okay. And is the same true with respect to the questions that you were asked about the

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complications that you had seen in your practice?
A. Absolutely.
Q. And did you attempt to the best of your ability as you sit here today to answer those questions as truthfully as you could?
A. I attempted to answer them to the best of my ability.
Q. Okay. You recall counsel asking you questions whether or not you had reviewed certain Ethicon internal documents?
A. Yes.
Q. Okay. Do you recall in the course of preparing your report reviewing Ethicon internal documents that discussed or mentioned at least the potential for roping of mesh?
A. Yes.
Q. Do you recall reviewing Ethicon internal documents that mention the potential for fraying of mesh?
A. Yes.
Q. Do you recall reviewing internal Ethicon documents that mention potential for particle loss?
A. Yes.
Q. Do you recall reviewing Ethicon internal documents that mention the potential for

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cytotoxicity?
A. Yes.
Q. Do you recall reviewing Ethicon internal documents that mention the potential and possibility of degradation?
A. Yes.
Q. Did you consider those documents that you reviewed in forming the opinions that are set forth in your expert report and that you've testified about today?
A. I considered those in addition to the literature that is available to me within the scientific community.
Q. And considering the materials that you reviewed, do you hold your opinions set forth in your report and that you've testified today to a reasonable degree of medical certainty?
A. I do.
Q. And counsel didn't show you any documents to confirm whether or not you recall reviewing any particular documents about roping, fraying, particle loss, cytotoxicity or degradation, did she?
A. No, she didn't.
Q. And counsel asked you a number of questions about different, what I'll refer to as

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design issues, but potential for fraying, particle loss, cytotoxicity, roping, perhaps curling. Do you recall those questions about the nature of the mesh and the design of the mesh?

A. I do recall them.

Q. And have you addressed many of the topics that she asked you about today in your expert report?

A. I have.

Q. Okay. And are the basis for your opinions set forth in your expert report?

A. They are.

Q. Okay. Dr. Pulliam, if I told you that CFR stands for Code of Federal Regulations, would that impact your opinions in any way?

A. No, it would not.

Q. And Dr. Pulliam, the opinions that you've given in response to counsel's questions today, have those been opinions that you hold to a reasonable degree of medical certainty?

A. They are.

Q. And are those based on your training, experience, knowledge, discussions with -- let me ask -- strike that.

What are your opinions based on that you've testified about today?

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A. They're based on my review of the medical literature, my clinical experience, my training, on my attendance at national and local meetings, and on my discussions with peers.

Q. Okay. Thank you. That's all the questions. For now.

MS. WHITE: I don't think I have anything.

(Off record discussion.)

COURT REPORTER: Do you want a rough draft?

MS. WHITE: Yes.

(The deposition was concluded at 4:15 p.m.)

(Signature reserved.)

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STATE OF NORTH CAROLINA
COUNTY OF MECKLENBURG

I, Karen K. Kidwell, RMR, CRR, CLR, in and for the State of North Carolina, do hereby certify that there came before me on Friday, March 31, 2017, SAMANTHA JOY PULLIAM, M.D., who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge concerning the matters in controversy in this cause; that the witness was thereupon examined under oath, the examination reduced to typewriting under my direction, and the deposition is a true record of the testimony given by the witness.

I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto or financially interested in the action.

This the 4th day of April, 2017.

_____

Karen K. Kidwell, RMR, CRR, CLR
Notary Public #19971050142

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ACKNOWLEDGMENT OF DEPONENT

I, SAMANTHA JOY PULLIAM, M.D., do hereby certify that I have read the foregoing pages and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheets.

_____

SAMANTHA JOY PULLIAM, M.D. Date

Subscribed and sworn to before me this ____ day of_____, 2017.

_____

Notary Public
My Commission Expires: